

EPA Jacket 2382-188

Material Sent for Data Extraction

Reg # 2382- RIT

Description: Product Registration

☐ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 7-6-12

☐ Notification Dated _____

☐ New CSF(s) Dated _____

☐ Other: _____

☐ Decision #: _____


☐ Other Action/Comments: _____

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: REGINA FOUSHEE-Smith

Phone: 605-0780 Division: RD

Date: _____

 <p align="center">ENVIRONMENTAL PROTECTION AGENCY</p> <p align="center">Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460</p>	<p>EPA Registration No.</p> <p align="center">2382-188</p>	<p>Date of Issuance:</p> <p align="center">July 6, 2012</p>
<p align="center">NOTICE OF PESTICIDE:</p> <p align="center"> <input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration </p> <p align="center">(under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</p>	<p>Term of Issuance:</p> <p align="center">Unconditional</p> <hr/> <p>Name of Pesticide Product:</p> <p align="center">EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS</p>	
<p>Name and Address of Registrant (include ZIP Code):</p> <p>Virbac Animal Health, Inc. P.O. Box 162059 Fort Worth, TX 76161</p>		
<p>Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.</p>		
<p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.</p> <p>Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> <p>This action is taken under the authority of section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Registration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.</p> <p align="center">Terms of Registration</p> <ol style="list-style-type: none"> EPA has registered the product listed above provided that the following change is made to the label before you release the product for shipment: Revise the EPA Registration Number to read: "EPA Registration No 2382-188." The Net Contents must be displayed in accordance with the description identified in the Labeling Consistency Committee's clarification. This information may be located at the following Agency web site under miscellaneous http://www.epa.gov/opp00001/regulating/labels/label_review_faq.htm#miscellaneous. "Regarding listing net contents - Net weight or contents must be stated on a pesticide label in accordance with FIFRA (2)(q)(2)(C)(iii) and 40 CFR 156.10(a)(1)(iii). EPA interpretation of the statutory and regulatory requirements is that the label must state the total weight for the entire contents as sold and distributed. In 		
<p>Signature of Approving Official:</p> <p align="center">Refer to Page 3</p> <p>Richard J. Gebken, Product Manager (10) Registration Division, Insecticide Branch</p>	<p>Date:</p> <p align="center">July 6, 2012</p>	

addition, the label may indicate the net weight and quantity of individual units within the carton. For example, "Net Weight 6.25 lbs. (20 - 5oz. packets)." For additional information regarding the Net Weight/Contents statement, please reference Chapter 17 of the Label Review Manual at <http://www.epa.gov/oppfead1/labeling/lrm/chap-17.htm>."

3. This registration is time-limited and expires two years from the date this product is first released for shipment. You must provide the Agency with a projected "release for shipment date", in writing within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected "release for shipment date" until an actual release for shipment date is provided in writing.
4. Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i.e., no alternate formulations or minor formulation amendments will be submitted and/or approved for this product, except to allow for alternate sources of any individual inert ingredient).
5. You must submit the following data within the timeframe described below:
Within sixteen (16) months of the date on this Notice of Registration, provide to the Agency acceptable data packages for Guideline Studies: OPPTS 830.6320 (Corrosion Characteristics) and OPPTS 830.6317 (Storage Stability).
6. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on August 1, 2012. The quarterly reports are due two months after the end of each quarter. Please flag any Confidential Business Information (CBI) as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kimberly Nesci).

The following is a list of information that must be included in the quarterly reports for each incident:

- EPA Registration Number
- Product name (brand name)
- Lot#
- Where purchased: internet, store, Veterinarian
- Active Ingredient(s)
- Weight range for product
- Date on which incident occurred, (mm/dd/yyyy)
- State in which the incident occurred, (standard 2 letter abbreviation)
- Registrant case #
- Species: dog, cat, other (specify)
- Breed: (as reported by pet owner)
- Age: months or years
- Sex: M, F, or neutered
- Weight: pounds
- Primary Route of Exposure: dermal, oral, other animal, inhalation, other
- Body System: neurological, dermatological, GI, respiratory, ocular, other Major signs noted with separate column for each sign, using standard terminology
- Time to Onset: (hours, days)
- Treated by veterinarian: yes or no
- First time product used: yes or no
- Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
- Any known precondition
- EPA Severity Code: death, major, moderate, minor
- Outcome: died, recovered, still treated, unknown

7. Along with the enhanced incident reporting, you must submit an analysis of all incidents seen, to include the following details:
 - a. All minor dermal and ocular irritation reports.
 - b. Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - c. A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
 - d. Summary table for dogs and table for cats showing number of incidents that are believed due to

secondary exposure (e.g., multi-pet households).

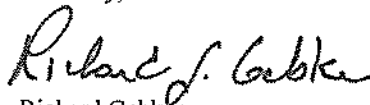
- e. A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
 - f. A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
 - g. A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
 - h. Table showing number of incidents for each dog breed.
 - i. Table showing number of incidents in dogs for each clinical sign.
 - j. Table showing number of incidents in dogs for each organ system.
 - k. Report aggregate incidents, but do not combine moderate and minor incidents.
8. If EPA determines that future mitigation measures are necessary for all pet spot-on products, the Agency will inform all registrants concerned. If mitigation measures are necessary, EPA may take regulatory action.
9. Virbac Inc. should adequately address all of the mitigation actions identified in the Agency's *Generic Pet Spot-On Mitigation Plan* available at the following internet site: <http://www.epa.gov/pesticides/health/spot-on-meetings.html>.

You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for registration review of your product under FIFRA.

Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If you fail to comply with all of the **Terms of Registration** stated above, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e) and/or automatically expire. Your release for shipment of the product constitutes your acceptance of these conditions.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. If you have any questions concerning this action, please contact me Richard J. Gebken at (703) 305-6701 or gebken.richard@epa.gov.

Sincerely,



Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7505C)

Enclosure

{Master Label}
Virbac's Master Label

Date December 13, 2011 Version US-7 EPA Reg. No. 2382-XXX
Fipronil + Pyriproxyfen Topical Solution for Cats

Virbac

EFFIPRO[®] PLUS TOPICAL SOLUTION FOR CATS

FOR USE ONLY ON CATS AND KITTENS 8 WEEKS OLD OR OLDER

ACTIVE INGREDIENTS:

Fipronil..... 9.5%
Pyriproxyfen..... 1.5%

OTHER INGREDIENTS: 79.0%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION
READ ENTIRE LABEL BEFORE EACH USE

ACCEPTED
with COMMENTS
In EPA Letter Dated

July 6, 2012

*Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
2382-188*

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on kittens under 8 weeks of age. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Possible temporary irritation may occur at the site where EFFIPRO[®] PLUS Topical Solution for Cats was applied. Contact a veterinarian immediately if signs become persistent or become more severe during the first few days following application. If an unusual reaction is observed following initial application, a veterinarian should be consulted before repeating application. Certain medications can interact with pesticides.

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents.	

DIRECTIONS FOR USE

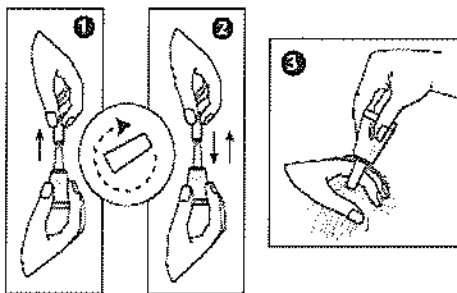
It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE.

FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON DOGS, PUPPIES, OR RABBITS. DO NOT USE ON OTHER ANIMALS.

For killing fleas, flea eggs, flea larvae, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that [which] may transmit [carry] Lyme disease), mosquitoes, and chewing lice; apply to CATS or KITTENS (8 weeks old or older) as follows:

APPLICATION DIRECTIONS

1. Remove one applicator from packaging.
Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator tip.
Push cap down to break seal.
Remove cap prior to treatment application.
3. Part cat's hair between shoulder blades until skin is visible.
Place applicator tip directly against exposed skin.
Deposit entire contents by squeezing the applicator at a single site on cat's skin.
Ensure that EFFIPRO® PLUS Topical Solution for Cats is not applied superficially on cat's hair.



FREQUENCY OF APPLICATION

EFFIPRO® PLUS Topical Solution for Cats will kill fleas, ticks and chewing lice when applied monthly.

Fleas: EFFIPRO® PLUS Topical Solution for Cats can control fleas for up to six weeks. Apply monthly if your cat has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely. EFFIPRO® PLUS Topical Solution for Cats can control flea eggs (and larvae) for up to three months (90 days).

Ticks: EFFIPRO® PLUS Topical Solution for Cats can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.

Chewing Lice: EFFIPRO® PLUS can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Cats can kill mosquitoes within 24 hours (for up to 14 days), and within 48 hours (for up to 28 days).

Notes: Wait at least 30 days before re-application of EFFIPRO® PLUS Topical Solution for Cats. Avoid contact with treated area until dry.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE /CONTAINER DISPOSAL: If empty: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND DISCLAIMER

To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this product not in accordance with directions. Buyer and user assume all risks of use and handling of this material when such use and handling are contrary to label instructions. To the extent consistent with applicable law, any damage arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.

Net Contents: 1, 3, 6 or 36 single-dose applicator(s) per package. Each applicator contains 0.017 fl oz (0.5 mL) of solution.

(Detachable) calendar (monthly application) reminder stickers with (illustration of cat or kitten).

EPA Reg. No. 2382-XXX

EPA Est. No. 2382-XXX

VIRBAC AH, INC.
PO BOX 162059

FORT WORTH, TX 76161
1-800-338-3659

Made in France
EFFIPRO® is a registered trademark of Virbac S.A. in the United States.
Questions or comments?
Call: 1-800-338-3659

{Text for Front Panel, Back Panel and Side Panel}

See package insert(s) for directions for use and frequency of application
Open resealable label for directions for use
Open resealable label for directions for use and storage and disposal
See back panel for additional precautionary statements
See package insert(s) for frequency of application
See enclosed insert(s) for directions for use and storage and disposal
See enclosed insert(s) for directions for use

Use only on cats
For Use on Cats only
Only for cats and kittens 8 weeks old or older
(1, 3, 6 or 36) applicator(s) 0.017 fl oz (0.5 ml)

Photograph of cat or kitten

Lift here to open (LIFT HERE TO OPEN)

{Text for Foil of Blister package}

Virbac
EFFIPRO® PLUS Topical Solution for Cats
Only for use on cats / 0.017 fl oz (0.5 ml)
Contains fipronil (9.5%) and pyriproxyfen (11.5%)
KEEP OUT OF REACH OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-XXX

{Text for Applicator Tube}

Virbac
EFFIPRO® PLUS
Topical Solution for Cats
Only for use on cats
0.017 fl oz (0.5 mL)
Contains fipronil (9.5%) and pyriproxyfen (11.5%)
KEEP OUT OF REACH
OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-XXX

MARKETING CLAIMS

[Multiple infestations]

- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea larvae, ticks, mosquitoes and chewing lice (for CATS and KITTENS 8 weeks old or older).
- For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing lice (for CATS and KITTENS 8 weeks old or older).
- EFFIPRO® PLUS Topical Solution for Cats contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice (on cats) (8 weeks old or older).
- EFFIPRO® PLUS Topical Solution for Cats contains the active ingredient pyriproxyfen, which controls reinfestation caused by flea eggs, flea larvae (on cats) (8 weeks old or older).
- For killing fleas, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks, (which may carry (transmit) Lyme disease), mosquitoes and chewing lice; apply to CATS or KITTENS (8 weeks old or older) as follows: (followed by application directions).
- Persistent flea and tick efficacy for up to one month (4 weeks) (30 days)

- Prevents flea and tick (re-)infestation for up to one month (4 weeks)
- Effective monthly application for (on) fleas and ticks
- Effective monthly application for cats (and kittens) against fleas and ticks
- Kills fleas and ticks for up to one month (4 weeks)
- Kills fleas, ticks, mosquitoes and chewing lice
- Kills fleas, ticks, mosquitoes and lice
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes and chewing lice
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes and lice
- Apply monthly for control and prevention of fleas and ticks
- Protects against fleas and ticks for up to one month
- EFFIPRO® PLUS Topical Solution for Cats will kill fleas, ticks and chewing lice when applied monthly.
- Fleas: EFFIPRO® PLUS Topical Solution for Cats can control fleas, flea eggs and flea larvae for up to (six weeks)
- Apply monthly if your cat has fleas that may cause Flea Allergy Dermatitis, or if reinfestation is likely.
- Ticks: EFFIPRO® PLUS Topical Solution for Cats can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.
- Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Cats can kill mosquitoes within 24 hours (for up to 14 days), and within 48 hours (for up to 28 days).
- Notes: Wait at least 30 days before re-application of EFFIPRO® PLUS Topical Solution for Cats. Avoid contact with treated area until dry.

[Fleas]

- Kills newly emerged adult fleas prior to egg-laying
- Kills fleas that may transmit bartonellosis
- Kills fleas that may transmit bartonellosis, tularemia and tapeworm
- Kills fleas that may transmit (bartonellosis), (tularemia) (and) (tapeworm)
- Kills fleas that may transmit (bartonellosis), (tularemia) (and) (tapeworm infestations)
- Kills fleas that may transmit bartonellosis and tularemia
- Kills fleas, flea eggs and flea larvae
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to (3 months) (90 days)
- Kills flea eggs for up to (3 months) (90 days)
- Sterilizes and kills fleas
- Sterilizes fleas for up to (3 months) (90 days)
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to (3 months) (90 days)
- With pyriproxyfen (IGR)* to break flea life cycle
- * insect growth regulator
- Dual Action(!): fipronil and pyriproxyfen (IGR) effectively breaks the flea life cycle
- Kill fleas that may cause Flea Allergy Dermatitis (FAD) or flea-bite anemia
- Effective monthly control of adult fleas
- Kills fleas
- Easy to apply, control of (for) fleas that lasts for up to 1 month (4 weeks)
- Protects (your cat and kitten 8 weeks of age or older) from fleas for up to one month (4 weeks)
- Protects from fleas for up to one month (4 weeks)
- Kills adult fleas for up to one month (4 weeks)
- Apply monthly (all year) for control and prevention of fleas
- Regular (monthly) use breaks the flea life cycle
- EFFIPRO® PLUS Topical Solution for Cats (rapidly) kills fleas that may cause Flea Allergy Dermatitis (FAD)
- EFFIPRO® PLUS Topical Solution for Cats kills fleas on your cat
- Kills adult fleas which may cause Flea Allergy Dermatitis (FAO)
- Kills fleas which/that may cause flea-bite anemia
- Fleas do not have to bite to die
- Protects your cat from flea infestation that may cause flea-bite anemia
- The successive feeding activity of fleas on cats may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis (FAD)
- Protects cats and kittens over 8 weeks of age from fleas for up to one month (4 weeks)
- Prevents flea (re-)infestation for up to one month (4 weeks)
- Prevents flea eggs from hatching or developing into larvae or adult stages (for up to 90 days (3 months))

[Ticks]

- Kills all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (including those which [that] may transmit (carry) Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis, anaplasmosis and cytauxzoonosis)
- Kills ticks, including those that may transmit Lyme disease
- Kills ticks including Deer ticks (which may transmit Lyme disease), American dog ticks (which may transmit Rocky Mountain Spotted Fever), Brown dog ticks (which may transmit ehrlichiosis), and Lone Star ticks (which may transmit hepatozoonosis) for up to one month (4 weeks)
- Kills ticks including Deer ticks (which may transmit Lyme disease), American dog ticks (which may transmit Rocky Mountain Spotted Fever) and Brown dog ticks (which may transmit ehrlichiosis) for up to one month (4 weeks)
- Kills Brown dog ticks (*Rhipicephalus* spp), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp), and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks)
- Kills Lone Star ticks (*Amblyomma americanum*) for up to 4 weeks (for up to one month)

- Protects Cats and kittens from ticks for up to one month

[Mosquitoes]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days

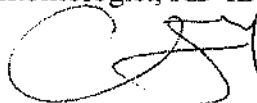
[All others]

- Chewing lice infestations are rapidly eliminated
- May be used only on kittens from 8 weeks of age
- Begins working upon application
- Once monthly application
- Single application lasts up to 4 weeks (one month)
- Easy and convenient application (applications)
- Easy to apply spot-on (topical) application
- Convenient, easy to apply
- Convenient to use (easy to apply)
- Convenient to use (easy to apply) topical application
- Convenient topical application (for cats)
- Easy, spot-on (topical) application
- Quick drying, non-greasy
- Available from licensed veterinarians
- 1 (3, 6, 36) applicator(s) (tube[s]) of 0.017 fl oz (0.5 mL)
- 1 (3, 6, 36) applicator(s) (tube[s]) 0.017 fl oz (0.5 mL)
- 1 (3, 6, 36) month(ly) dose(s) (application[s])
- 1 applicator (tube) 1 month(ly) dose
- 3 applicators (tubes) 3 (monthly) doses
- 6 applicators (tubes) 6 (monthly) doses
- 36 applicators (tubes) 36 (monthly) doses
- 1 applicator containing 0.017 fl oz (0.5 mL)
- 3 (6, 36) applicators each containing 0.017 fl oz (0.5 mL)
- Remains effective after exposure to sunlight
- Remains effective after bathing
- Remains effective even after bathing, water immersion or exposure to rain or sunlight
- Remains effective even after bathing
- Remains effective after exposure to rain and sunlight
- Still works after bathing, or exposure to sunlight
- EFFIPRO® PLUS Topical Solution for Cats is effective after bathing, shampooing, water immersion, or sunlight exposure.
- Still works after exposure to sunlight
- Waterproof (remains effective after bathing and swimming)

Efficacy Review

Date: June 19, 2012

Efficacy Reviewer: Clayton Myers, Ph.D., Entomologist, RD-IB
myers.clayton@epa.gov
703-347-8874



6-19-12

Risk Manager Rev.: Bonaventure Akinlosotu

Products: EFFIPRO Plus Topical Solution for Cats

EPA Reg. #: 2382-R11

A.I.'s: Fipronil (9.5%), Pyriproxyfen (11.5%)

Decision #s: 458840

DP #s: 398337

Submission: R310, New Products, RD Science Review

MRIDs: Submitted: 48696915, 48695015, 48695016, 48695017

Cited: 43121114, 43121115, 43121116, 43121118, 43121119, 43121120, 43121121, 43121122, 43444901, 43577701, 43577712, 43577713, 43951701, 44088901, 44942011, 44942106, 45620502, 45620503, 45628104, 45628105, 44850104, 43577712, 43121114, 43121115, 43121117, 43121122, 45620501, 45628101, 45628102, 45628103, 45628201, 45628103, 45628201, 45866902, 46019201, 46019201, 46006002, 46019201, 46019202,

GLP: Not all

Summary/Discussion of Submitted and Cited Efficacy Data:

Efficacy claims are supported for control the following pests on cats for one month:

1. Fleas (adults, eggs, and larvae). A six week duration claim is supported for flea adults, as it is caveated that treatment should be applied every four weeks under high flea pressure (same as claims accepted for pioneer fipronil products). Claims against flea eggs, flea larvae, prevention of all flea life stages, and breaking of the flea life cycle are supported for 3 months (90 days).
2. Ticks (all stages, including Ticks that may transmit Lyme Disease)
3. Mosquitoes
4. Chewing Lice

5. Submitted MRID's are summaries and/or extraneous to data requirements and are rated as supplemental.

Specific Review of Label Claims and Directions:

1. Throughout the label, for the mosquito claims related to speed of kill, "Kills mosquitoes within 24 hours for up to 7 days and within 48 hours for up to 28 days", all parentheses must be removed, as this implies optional text for the durations of control.
2. Throughout the label, all references to disease claims which are open ended must be revised to only refer to specific diseases that may be transmitted by the targeted pest. For example, all text that can be interpreted as all-inclusive such as "including" prior to a list of diseases must be deleted.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of Chemical Safety and Pollution
Prevention

Office of Pesticide Programs
Registration Division (7505P)

CHILD RESISTANT PACKAGING REVIEW

April 17, 2012

MEMORANDUM

Subject: Name of Pesticide Products: Effipro PLUS Topical Solution for Cats;
Effipro PLUS Topical Solution for Dogs
Product Type: Insecticide (fleas, brown dog ticks, American
dog ticks, Lone Star ticks and Deer ticks,
mosquitos and chewing lice)
EPA File Symbols: 2382-RII, -RIO
DP Barcodes: D398339, D398345, D398776
Decision Nos.: 458840, 459013
MRIDs : none
Action Code: R310
PC Codes: 129121 Fipronil
129032 Pyriproxyfen

From: Breann Hanson, Biologist *B Hanson*
Technical Review Branch (TRB)
Registration Division (RD; 7505P)

Through: Rosalind Gross, Ph.D. *Rosalind I Gross*
TRB
RD; 7505P

To: Bonaventure Akinlosotu, RM Team 10
Insecticide Branch
Registration Division (7505P)

Applicant: Virbac AH, Inc.

FORMULATIONS FROM LABELS:

Effipro PLUS Topical Solution for Cats; EPA File Symbol: 2382-RII

Active Ingredients:	% by wt
129121 Fipronil	9.5
129032 Pyriproxyfen	11.5

Effipro PLUS Topical Solution for Dogs, EPA File Symbol: 2382-RIO

Active Ingredients:	% by wt
129121 Fipronil	9.7
129032 Pyriproxyfen	2.9

SUMMARY: Based on the CRP Child Resistant Packaging (CRP) data previously reviewed by TRB (R. Gross, DP Barcodes: D379880, D381039, D379873 and D381040, EPA File Symbols: 2382-RIL, 2382-RIA, 1/NOV/2010; and B. Hanson, DP Barcodes: D388132, D388130, EPA Reg. Nos. 2382-185, -186, 5/JUL/2011), all Senior Adult Use Effectiveness (SAUE) and Child Resistant Effectiveness (CRE) CRP testing data requirements have been met for the 1-, 3-, 6- and 36-tube package presentations for the 0.67 mL fill volume, the 1.34 mL fill volume, the 2.68 mL fill volume and the 4.02 mL fill volume for EPA File Symbol: 2382-RIO; as well as the 1-, 3-, 6- and 36- tube presentations for the 0.5 mL fill volume for EPA File Symbol: 2382-RII. All CRP Certifications for the aforementioned sizes for EPA Reg. Nos. 2382-RII and 2382-RIO are acceptable. The labels submitted for 2382-RII (dated 13/DEC/2011) and 2382-RIO (dated 14/DEC/2011) have the same instructions as those used in the SAUE testing for both 2382-185, -186 (see "Packaging" section, below).

ACTION REQUESTED: The Risk Manager requests that TRB review applications for two new products, Effipro PLUS Topical Solution for Cats, EPA File Symbol: 2382-RII, and Effipro PLUS Topical Solution for Dogs, EPA File Symbol: 2382-RIO. The products are similar to two currently registered products, EPA Reg. Nos. 2382-185 and -186 except the proposed products also contain the IGR pyriproxyfen. The registrant is citing the CRP data used in registration of 2382-185, -186.

BACKGROUND: Virbac AH, Inc. (herein the "registrant") has applied to register 2 proposed products; for Effipro PLUS Topical Solution for Cats, EPA File Symbol: 2382-RII, and Effipro PLUS Topical Solution for Dogs, EPA File Symbol: 2382-RIO. Both proposed products are labeled for control of fleas, brown dog ticks, American dog ticks, Lone Star ticks and Deer ticks, mosquitos and chewing lice in dogs/puppies.

According to information provided by the registrant, both of the proposed products employ the same single dose unit applicators that were previously CRP tested for 2382-185 and -186. Those packages consisted of a white plastic tube with a white closure containing a pin and came in 3 different tube sizes with 5 fill levels. The proposed products will also use the same tube type and come in the same fill levels but will contain fipronil and pyriproxyfen. The tubes will consist of a 1 mL size tube with 0.5 mL of product for EPA File Symbol: 2382-RII; or a 1 mL size tube with 0.67 mL product, a 3 mL size tube with 1.34 mL or 2.68 mL product, or a 6 mL size tube with 4.02 mL product for EPA File Symbol: 2382-RIO. The tubes come in packages of 1-tube, 3-tubes, 6-tubes, or 36-tubes.

The registrant has submitted CRP Self-Certification letters for both 2382-RII (dated 16/DEC/2011) and 2382-RIO (dated 19/DEC/2011).

PREVIOUS CONCLUSIONS of CITED CRP STUDIES: Based on the conclusions encompassing the two previous TRB memorandums for EPA Reg. Nos. 2382-185, -186 (R. Gross, DP Barcodes: D379880, D381039, D379873 and D381040, EPA File Symbols: 2382-RIL, 2382-RIA, 1/NOV/2010; and B. Hanson, DP Barcodes: D388132, D388130, EPA Reg. Nos. 2382-185 2382-186, 5/JUL/2011), all Senior Adult Use Effectiveness (SAUE) and Child Resistant Effectiveness (CRE) CRP testing data requirements were met for the 1-, 3-, 6- and 36-tube package presentations for the 0.67 mL fill volume, the 1.34 mL fill volume, the 2.68 mL fill volume and the 4.02 mL fill volume for EPA Reg. No. 2382-185; as well as the 1-, 3-, 6- and 36- tube presentations for the 0.5 mL fill volume for EPA Reg. No. 2382-186.

PACKAGING: The following description of the package is taken from a previous TRB memorandum (B. Hanson, DP Barcodes: D388132, D388130, EPA Reg. Nos. 2382-185 2382-186, 5/JUL/2011):

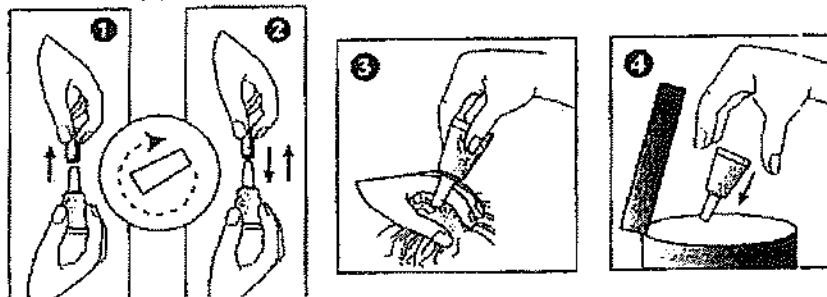
The package is a white plastic tube with a white closure containing a pin. The tube has a neck (cannula), which is sealed. The closure fits onto the tube neck. There is a pin recessed from the top of the closure. The closure pulls off the tube and is inverted and pushed down for the pin to puncture the tube neck. The closure is then removed to release the product. The tube is the child-resistant feature.

The tubes come in 3 different sizes with 5 fill levels of product: a 1 mL size tube with 0.5 mL product for EPA File Symbol: 2382-RII; and a 1 mL size tube with 0.67 mL product, a 3 mL size tube with 1.34 mL or 2.68 mL product, or a 6 mL size tube with 4.02 mL product for EPA File Symbol: 2382-RIO. The tubes will come in packages of 1-, 3-, 6-, or 36-tube configurations.

The labels submitted for 2382-RII (dated 13/DEC/2011) and 2382-RIO (dated 14/DEC/2011) have the same instructions as those used in the previous SAUE testing for both 2382-185, -186 (see below).

The instruction given to seniors during CRP testing directed Seniors to "Please open one tube according to directions 1 & 2 on this paper....." and the Seniors were provided the package insert and directed to the following instructions (from MRID 484100-02, 1710-057):

1. Remove one applicator from packaging. Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator tip. Push cap down to break seal. Remove cap prior to treatment application.
3. Part pet's hair between shoulder blades until skin is visible. Place applicator tip directly against exposed skin. Squeeze applicator to apply entire contents to a single spot on pet's skin. Avoid superficial application to pet's hair.
4. Discard empty applicator into ordinary household trash.



TOXICITY:

The toxicity of the product is based on the toxicity of Fipronil. The toxic or harmful amount of Fipronil for an 11.4 kg child is $2.5 \text{ mg/kg} \times 11.4 \text{ kg} = 28.5 \text{ mg}$.

Effipro PLUS Topical Solution for Cats; EPA File Symbol: 2382-RII: Access to a toxic or harmful amount = 28.5 mg divided by $[1046.3 \text{ mg/mL} \times 0.095 \text{ Fipronil}] = 0.286 \text{ mL} = 0.29 \text{ mL}$.

Effipro PLUS Topical Solution for Dogs; EPA File Symbol: 2382-RIO: Access to a toxic or harmful amount = 28.5 mg divided by $[1032.5 \text{ mg/mL} \times 0.097 \text{ Fipronil}] = 0.28 \text{ mL} = 0.28 \text{ mL}$.

Access to one tube represents a failure for a child for all sizes equal to or greater than 0.29 mL for EPA File Symbol: 2382-RII, and for all sizes equal to or greater than 0.28 mL for EPA File Symbol: 2382-RIO.

Toxicity, Child Failure, and Package

EPA File Symbol	mL ^a	fl. oz. ^b	Product Density (mg/ml)	% Fipronil	mg Fipronil	# unit = tox /harmful amt
2382-RII	0.5	0.017	1046.3	9.5	49.7	1
2382-RIO	0.67	0.023	1032.5	9.7	67.1	1
2382-RIO	1.34	0.045	1032.5	9.7	134.2	1
2382-RIO	2.68	0.09	1032.5	9.7	268.4	1
2382-RIO	4.02	0.136	1032.5	9.7	402.6	1

^a 1 mL = 0.0338 fl. oz

^b 1 fl. oz. = 29.6 mL

FAILURE: For the purposes of CRP testing a **child failure** is access to 1 unit. Access to 1 unit is more than 28.5 mg of Fipronil for all sizes equal to or greater than 0.29 mL for EPA File Symbol: 2382-RII, or equal to or greater than 0.28 mL for EPA File Symbol: 2382-RIO.

A **unit failure** is opening the tube or any partial or complete access to the placebo (water).

A **Senior Adult Use Effectiveness failure** is failure to access the tube contents in the prescribed test time of 5 minutes for the first package or 1 minute for the second package, not accessing the tube contents in the correct manner in the prescribed test time of 5 minutes for the first package or 1 minute for the second package, not understanding the directions, or not opening the tube.

CURRENT SUBMISSION: The registrant has submitted data matrices for both 2382-RII (dated 16/DEC/2011) and -RIO (dated 6/FEB/2012).

EPA File Symbol: 2382-RII:

- The submitted data matrix for 2382-RII cites the below noted MRIDs to fulfill all CRE and SAUE data requirements for the 1 mL tube, 0.5 mL fill volume for the 1-, 3-, 6, and 36-tube configurations.

Tube Size	Fill Volume	Tube Presentation	Company Data		MRID	Study Acceptable
mL	mL	# Tubes/ Pkg.	CRE	SAUE		
1	0.5	1	X		48095215	Yes ^a
1	0.5	1		X	48095218	Yes ^a
1	0.5	3	X		48410018	Yes ^b
1	0.5	3		X	48410019	Yes ^b
1	0.5	6	X		48095216	Yes ^b
1	0.5	6		X	48095219	Yes ^a
1	0.5	36	X		48095217	Yes ^a
1	0.5	36		X	48095220	Yes ^a

^a R. Gross, DP Barcodes: D379880, D381039, D379873 and D381040, EPA File Symbols: 2382-RIL, 2382-RIA, 1/NOV/2010

^b B. Hanson, DP Barcodes: D388132, D388130, EPA Reg. Nos. 2382-185 2382-186, 5/JUL/2011

EPA File Symbol: 2382-RIO:

- The submitted data matrix for 2382-RIO cites the below noted MRIDs to fulfill all CRE and SAUE data requirements for the 1 mL tube, 0.67 mL fill volume for the 1-, 3-, 6, and 36-tube configurations.

Tube Size	Fill Volume	Tube Presentation	Company Data		MRID	Study Acceptable
mL	mL	# Tubes/ Pkg.	CRE	SAUE		
1	0.67	1	X		48410001	Yes ^a
1	0.67	1		X	48410002	Yes ^a
1	0.67	3	X		48410007	Yes ^a
1	0.67	3		X	48410008	Yes ^a
1	0.67	6	X		48410003	Yes ^a
1	0.67	6		X	48410004	Yes ^a
1	0.67	36	X		48410005	Yes ^a
1	0.67	36		X	48410006	Yes ^a

^a B. Hanson, DP Barcodes: D388132, D388130, EPA Reg. Nos. 2382-185 2382-186, 5/JUL/2011

- The submitted data matrix for 2382-RIO cites the below noted MRIDs to fulfill all CRE and SAUE data requirements for the 3 mL tube, 1.34 mL fill volume for the 1-, 3-, 6, and 36-tube configurations.

Tube Size	Fill Volume	Tube Presentation	Company Data		MRID	Study Acceptable
mL	mL	# Tubes/ Pkg.	CRE	SAUE		
3	1.34	1	X		48095221	Yes ^a
3	1.34	1		X	48095224	Yes ^a
3	1.34	3	X		48410009	Yes ^b
3	1.34	3		X	48410010	Yes ^b
3	1.34	6	X		48095222	Yes ^a
3	1.34	6		X	48095225	Yes ^a
3	1.34	36	X		48095223	Yes ^a
3	1.34	36		X	48095226	Yes ^a

^a R. Gross, DP Barcodes: D379880, D381039, D379873 and D381040, EPA File Symbols: 2382-RIL, 2382-RIA, 1/NOV/2010

^b B. Hanson, DP Barcodes: D388132, D388130, EPA Reg. Nos. 2382-185 2382-186, 5/JUL/2011

- The submitted data matrix for 2382-RIO cites the below noted MRIDs to fulfill all CRE and SAUE data requirements for the 3 mL tube, 2.68 mL fill volume for the 1-, 3-, 6, and 36-tube configurations.

Tube Size	Fill Volume	Tube Presentation	Company Data		MRID	Study Acceptable
mL	mL	# Tubes/ Pkg.	CRE	SAUE		
3	2.68	1	X		48095227	Yes ^a
3	2.68	1		X	48410015	Yes ^b
3	2.68	3	X		48410011	Yes ^b
3	2.68	3		X	48410012	Yes ^b

3	2.68	6	X		48095228	Yes ^a
3	2.68	6		X	48095231	Yes ^a
3	2.68	36	X		48095229	Yes ^a
3	2.68	36		X	48410016	Yes ^b

^a R. Gross, DP Barcodes: D379880, D381039, D379873 and D381040, EPA File Symbols: 2382-RIL, 2382-RIA, 1/NOV/2010

^b B. Hanson, DP Barcodes: D388132, D388130, EPA Reg. Nos. 2382-185 2382-186, 5/JUL/2011

- The submitted data matrix for 2382-RIO cites the below noted MRIDs to fulfill all CRE and SAUE data requirements for the 6 mL tube, 4.02 mL fill volume for the 1-, 3-, 6, and 36-tube configurations.

Tube Size	Fill Volume	Tube Presentation	Company Data		MRID	Study Acceptable
mL	mL	# Tubes/ Pkg.	CRE	SAUE		
6	4.02	1	X		48095233	Yes ^a
6	4.02	1		X	48095236	Yes ^a
6	4.02	3	X		48410013	Yes ^b
6	4.02	3		X	48410014	Yes ^b
6	4.02	6	X		48095234	Yes ^a
6	4.02	6		X	48410017	Yes ^b
6	4.02	36	X		48095235	Yes ^a
6	4.02	36		X	48095238	Yes ^a

^a R. Gross, DP Barcodes: D379880, D381039, D379873 and D381040, EPA File Symbols: 2382-RIL, 2382-RIA, 1/NOV/2010

^b B. Hanson, DP Barcodes: D388132, D388130, EPA Reg. Nos. 2382-185 2382-186, 5/JUL/2011

CONCLUSION: Since a child failure is access to 1 unit for EPA File Symbols: 2382-RII, -RIO, as with EPA Reg. Nos. 2382-185, -186, and there are no changes to the type of packaging used, the use directions, and all the tube sizes and fill levels are the same, all SAUE and CRE CRP testing data requirements have been met for the 1-, 3-, 6- and 36-tube package presentations for the 0.5 mL fill volume for EPA File Symbol: 2382-RII; as well as the 1-, 3-, 6- and 36- tube presentations for the 0.67 mL fill volume, the 1.34 mL fill volume, the 2.68 mL fill volume and the 4.02 mL fill volume for EPA File Symbol: 2382-RIO. All CRP Self-Certifications are acceptable. The labels submitted for 2382-RII (dated 13/DEC/2011) and 2382-RIO (dated 14/DEC/2011) have the same instructions as those used in the previous SAUE testing for both 2382-185, -186.

Note to PM: MRIDs 48095230 and 48095232, both listed on the submitted data matrix, were deemed unacceptable in TRB's previous review per R. Gross. The studies were later resubmitted and given new MRIDs, 48410015 and 48410016, respectively. MRIDs 48095230 and 48095232 should be removed from the data matrix.

Note to Registrant: Should any human experience/epidemiological evidence indicate a problem once the product is in the marketplace, the Agency reserves the right to reexamine this data comprehensively and to question the child resistance of the package involved.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

May 15, 2012

MEMORANDUM

Subject: Name of Pesticide Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS
EPA Reg. No. /File Symbol: 2382-RII
DP Barcode: DP 398335
Decision No.: 458840
Action Code: R310
PC Codes: 129032 (Pyriproxyfen: 11.5%)
129121 (Fipronil: 9.5%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
May -15- 2012

To: Bonaventure Akinlosotu/Richard Gebken RM 10
Insecticide Branch
Registration Division (7505P)

W. Hashim
Team Leader - Tox

Registrant: VIRBAC AH, INC.

FORMULATION FROM LABEL:

Active Ingredient(s):	by wt.
129121 Fipronil	9.5%
129032 Pyriproxyfen	11.5%
Other Ingredient(s):	79.0%
TOTAL	100.0%

ACTION REQUESTED: The Risk Manager requests:

"For your review: R310. MRID 486950-10 to -14; for a Fipronil + Pyriproxyfen containing Spot-On for cats. Similar to 2382-186, except it contains the IGR pyriproxyfen. Submits prod chem., tox, efficacy and CAS data..."

BACKGROUND:

The material received for review includes a proposed label, indicating the product is packaged in single-use applicators (1, 3, 6 or 36 applicators per package; each applicator contains 0.017 fl. oz. or 0.5 mL of solution) for use on cats and kittens 8 weeks of age and older. Labeling includes the statement: "Wait at least 30 days before reapplication of EFFIPRO® PLUS Topical Solution for Cats." There are five acute toxicity studies (MRID 48695010, acute oral toxicity study in rats; 48695011, acute dermal toxicity study in rats; 48695012, acute eye irritation study in rabbits; 48695013, acute dermal irritation study in rabbits; and 48695014, contact hypersensitivity in albino guinea pigs, Buehler test), and a waiver request for the inhalation toxicity study requirement.

COMMENTS AND RECOMMENDATIONS:

1. The acute toxicity studies in MRIDs 48695010-48695014 were reviewed by a contractor, Summetic. The resulting DER was reviewed by TRB, and the appropriate revisions, if necessary, were made. It is concluded that these five acute toxicity studies are acceptable, and can be used to support the registration of 2382-R1I.
2. TRB has reviewed the acute inhalation toxicity study waiver request, and concludes that, based on the proposed product use and minimal potential inhalation exposure, this study can be waived and the product can be assigned to Toxicity Category IV by the inhalation exposure route.
3. Based on the results of the acute toxicity studies, the following is the acute toxicity profile for 2382-R1I (EFFIPRO PLUS TOPICAL SOLUTION FOR CATS):

Acute oral toxicity	III	Acceptable	MRID 48695010
Acute dermal toxicity	III	Acceptable	MRID 48695011
Acute inhalation toxicity	IV	Waived	n/a
Primary eye irritation	III	Acceptable	MRID 48695012
Primary dermal irritation	IV	Acceptable	MRID 48695013
Dermal sensitization	Negative	Acceptable	MRID 48695014

4. Based on the acute toxicity profile above, the following is the precautionary and first aid labeling for 2382-R1I, as obtained from the TRB Label Review System.

PRODUCT ID #: 002382-00188

PRODUCT NAME: EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse. [Wear protective eyewear.]*

*[Protective eyewear may be specified, if appropriate].

First Aid:

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician". The following statements are suggested types of information that may be included, if applicable: - technical information on symptomatology; - use of supportive treatments to maintain life functions; - medicine that will counteract the specific physiological effects of the pesticide; - company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

5. The basic CSF dated October 15, 2011 for 2382-RII should be reviewed and accepted by the TRB Chemistry Team.

DATA EVALUATION RECORD

PYRIPROXYFEN AND FIPRONIL

[104.15; EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS]

**STUDY TYPE: ACUTE ORAL TOXICITY - RAT [OCSPP 870.1100; OECD 425]
ACUTE DERMAL TOXICITY - RAT [OCSPP 870.1200; OECD 402]
ACUTE EYE IRRITATION - RABBIT [OCSPP 870.2400; OECD 405]
ACUTE DERMAL IRRITATION - RABBIT [OCSPP 870.2500; OECD 404]
DERMAL SENSITIZATION - GUINEA PIG [OCSPP 870.2600; OECD 406]
MRID: 486950-10, 486950-11, 486950-12, 486950-13, and 486950-14**

Prepared for
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
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9724 Kingston Pike, Suite 602
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Task Order No. 3-C-09

Primary Reviewer:
Donna L. Fefee, D.V.M.

Signature: Donna L. Fefee, AE
Date: APR 16 2012

Secondary Reviewers:
Thomas C. Marshall, Ph.D., D.A.B.T.

Signature: Thomas C. Marshall
Date: APR 16 2012

Robert H. Ross, M.S., Program Manager

Signature: Robert H. Ross
Date: APR 16 2012

Quality Assurance:
Angela M. Edmonds, B.S.

Signature: Angela M. Edmonds
Date: APR 16 2012

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

EPA Reviewer: Byron T. Backus, Ph.D.
Risk Manager (EPA): 10

Date: May 15, 2012

The following table is the Acute Toxicity Data Evaluation Record (DER) for the five studies and one waiver request submitted for the proposed product, File Symbol 2382-R11

1. DP BARCODE: 398335				
2. PC CODES: 129032, 129121				
3. CURRENT DATE: May 15, 2012				
4. TEST MATERIAL: 104.15; Batch FMA11123-6; 9.87% Fipronil and 12.03% Pyriproxyfen; colorless to yellowish liquid; density: 1.049 g/mL; pH: 7 (MRID 48695012) or 4-5 (MRID 48695013); expiration date: November 2011; stored at room temperature; expected to be stable under study conditions.				
Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity / rat Harlan Laboratories Ltd. (Itingen, Switzerland) Study #D34712 / October 20, 2011 OCSPP 870.1100; OECD 425	48695010	LD ₅₀ Females = 2000 mg/kg bw Four tested in accordance with AOT425 StatPgm (assumed sigma=0.5): 1 at 550 mg/kg, 3 at 2000 mg/kg. 550 mg/kg: no deaths, abnormal clinical signs, bw effects, or gross findings. 2000 mg/kg: 1 death (day 7 [dosed on day 1]); clinical signs: on day 1, ruffled fur in 3/3, decreased activity 1/3; one survivor had hunched posture, visible weight loss, and/or ruffled fur days 6-10; both survivors lost wt days 1-8 and gained days 8-15, but one had net wt loss over days 1-15; gross necropsy findings of hemorrhagic fluid in the lungs and abnormal black/brown jejunal contents in the decendent. <i>Deviations from OCSPP 870.1100/OECD 425: animals were 11-13 weeks of age, rather than 8-12 weeks of age; no rationale provided for use of starting dose different from default.</i>	III	A

Acute dermal toxicity / rat Harlan Laboratories Ltd. (Itingen, Switzerland) Study #D34723 / October 21, 2011 OCSPP 870.1200; OECD 402	48695011	LD ₅₀ > 2000 mg/kg (both sexes) No deaths, abnormal systemic clinical signs, or abnormal gross findings; BW affected: 5/5 females and 2/3 males lost weight during days 1-8 but had net BW gain over days 1-15; local effects: erythema on 2 males and 1 female day 2 (resolved by day 4), desquamation and/or focal crusts on all animals beginning days 5-7 (resolved by day 15). <i>Note: It is unclear whether the size of the dose site really was 10% of the body surface area (BSA). The study author stated that application sites were approximately 10% of body surface area, but it was also stated that application sites were covered by a gauze pad measuring ~25 cm², which, according to standard formulas, would be less than 10% of the BSA for rats in the BW range used in this study (202.1- 280.5 g).</i>	III	A
Acute inhalation toxicity / rat	n.a.	Waiver recommended on basis of product use (pet spot-on) and minimal inhalation exposure.	(IV)	W
Primary eye irritation / rabbit Harlan Laboratories Ltd. (Itingen, Switzerland) Study #D34734 / October 26, 2011 OCSPP 870.2400; OECD 405	48695012	Use of anesthetic not mentioned. No corneal or iridial effects seen. Conjunctival redness present in 3/3 eyes at 1 hr through 7 days and in 2/3 and 1/3 eyes at 10 and 14 days post instillation (score=1-2). Conjunctival chemosis and discharge seen at 1 hour, in 1 eye and 2 eyes, respectively (score=1), and not seen thereafter. Slight to moderate scleral reddening seen in 3 eyes at 1-24 hours and in 2 eyes at 48 and 72 hours. "Positive" conjunctivitis resolved within 72 hours. MMTS=4.67, at 1 hour; Mildly irritating (per Kay and Calandra). Classified based on resolution of "positive" irritation within 7 days or less.	III	A

Primary dermal irritation / rabbit Harlan Laboratories Ltd. (Ittingen, Switzerland) Study #D34745 / October 20, 2011 OCSP 870.2500; OECD 404	48695013	PDI at 72 hours=0.00 There were no observations of erythema, edema, or other dermal effects on any animal at any time point. "Nonirritant" based on US EPA (1988).	IV	A
Dermal sensitization / guinea pig Harlan Laboratories Ltd. (Fullinsdorf, Switzerland) Study #D34756 / October 28, 2011 OCSP 870.2600; OECD 406	48695014	Tested using Buehler method 100% (undiluted) test material used for induction and challenge. No irritation seen on any animal at any time point. <i>Not a sensitizer</i> Positive control study provided. <i>Deficiency: It appears that in the positive control study the testing lab was not able to identify the HNIC; two challenge concentrations (neither of which was a HNIC) were selected, based, in part, upon historical results. Results of initial challenge were equivocal, and a re-challenge was necessary. "Correct" results were attained, but the laboratory has not necessarily demonstrated proficiency.</i>	--	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap, W = Waived



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

May 18, 2012

MEMORANDUM

Subject: Name of Pesticide Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS
EPA Reg. No. /File Symbol: 2382-R11
DP Barcode: DP 398338
Decision No.: 458840
Action Code: R310
PC Codes: 129032 (Pyriproxyfen: 11.5%)
129121 (Fipronil: 9.5%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
May 18, 2012

To: Bonaventure Akinlosotu/Richard Gebken RM 10
Insecticide Branch
Registration Division (7505P)

T.L. Toxicology

Registrant: VIRBAC AH, INC.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129121 Fipronil	9.5%
129032 Pyriproxyfen	11.5%
<u>Other Ingredient(s):</u>	<u>79.0%</u>
TOTAL	100.0%

ACTION REQUESTED: The Risk Manager requests:

"For your review: R310. MRID 486950-18 & 19; for a Fipronil + Pyriproxyfen containing Spot-On for cats. Similar to 2382-186, except it contains the IGR pyriproxyfen. Submits prod chem., tox, efficacy and CAS data..."

BACKGROUND:

The material received for review includes a proposed label, indicating the product is packaged in single-use applicators (1, 3, 6 or 36 applicators per package; each applicator contains 0.017 fl. oz. or 0.5 mL of solution) for use on cats and kittens 8 weeks of age and older. Labeling includes the statement: "Wait at least 30 days before reapplication of EFFIPRO® PLUS Topical Solution for Cats." There are two documents for review, MRID 48695018 titled: "Summary of Companion Animal Safety Data for Effipro Plus Topical Solution for Cats (Fipronil 9.5% and Pyriproxyfen 11.5% End Use Product) and MRID 48695019 titled: "Tolerance Study by Cutaneous Application (Spot-On) in Young Cats." In addition, the data matrix indicates the registrant is citing the following additional MRIDs to satisfy the 870.7200 (cat) companion animal safety data requirements: 43272401, 43444904, 43577711, 43863801, 43121112, 44942009 (all from Merial) and 44850103.

COMMENTS AND RECOMMENDATIONS:

1. The following is a listing of the MRIDs cited by the registrant and the corresponding citation references as obtained from OPPIN and summaries from IHAD: MRID 43272401: Schwartz, E. (1994) Domestic Animal Safety Study of RM1601C 0.25% Topical Spray in Juvenile Cats: Interim Report: Lab Project Number: 94424. Unpublished study prepared by White Eagle Toxicology Lab. 112 p. [according to OPPIN the product supported by this study was 65331-EUP-1; there is no record of a review of MRID 43272401 in IHAD]; 43444904: Schwartz, E. (1994) Domestic Animal Safety Study of RM1601C Topical Spray (Frontline Spray Treatment) in Juvenile Cats: Lab Project Number: 94424: PS-234DAS. Unpublished study prepared by White Eagle Toxicology Labs. 168 p. [a DER for this study is in TXR 011405; groups of 4M & 4F domestic short hair kittens (≤ 8 weeks) were treated with either 1X (6 mL/kg), or 5X RM1601C (0.25% fipronil) at 1X (6 mL/kg), or with 5X the formulation vehicle; kittens were treated once a month for 3 months; the study demonstrated at least a 5X margin of safety in kittens]; 43863801: Cameron, D.; Maltby, B. (1995) Domestic Animal Safety by Topical Administration to Cats: Fipronil Spot Treatment: Lab Project Number: MRX 24/950746. Unpublished study prepared by Huntingdon Research Centre, Ltd. 174 p. [a summary for this study is in TXR 0051187; the test material was a 9.7% fipronil spot-on formulation, dosages tested: untreated control; vehicle control (5X); 1X, 3X and 5X once a month for 6 months. [From p. 20 of MRID 43863801 the 1X dose was 0.25 mL/kg; the 3X dose was 0.75 mL/kg and the 5X dose was 1.25 mL/kg. No treatment-related effects; animals were not treated at the indicated (presumably 0.5 mL) dosages until the fourth treatment when they were approximately 24 months (probably should be 24 weeks, as they were 12 weeks old at first treatment) old and the mean body weights for both males and females had reached 2.0 kg. HED classified the study as adequate since three treatments were applied at 0.5 mL]. MRID 43121112: Arnaud, J.; Consalvi, P. (1993) Domestic Animal Safety: Assessment of the Tolerance of a 0.25% RM 1601 Spray Formulation in Cats at 3, 9, and 15 mL/kg When Applied 6 Times to the Haircoat at 28 Day Intervals: Revised: Lab Project Number: CLI 137. Unpublished study prepared by Rhone Merieux, Inc. 62 p. [From TXR 0010923: Groups of three male cats were topically administered six treatments of the 0.25% fipronil formulation at dosages of either 0, 3, 9 or 15 mL/kg (0, 7.5, 22.5 and 37.5 mL/kg, respectively) at 28 day intervals; the proposed recommended dose for cats is 3-6 mL/kg... Classification: Unacceptable because: 1) the highest dosage level was not at 5X the highest recommended dose; 2) only three male cats per dosage group were included in the study; and 3) the study was not conducted in compliance with GLP regulations]. MRID 44942009: Clery, D. (1999) Fipronil/(S)-Methoprene/Topical/Solution/Target Species Safety Study in the Cat: Interim Final Report: Lab

Project Number: GB011/99-001: PR&D 0023301. Unpublished study prepared by Biological Labs. Europe Ltd. 127 p. {OPPTS 870.7200}[From TXR 5001487: a formulation containing fipronil, 10% w/v, and S-methoprene, 12% w/v, was topically applied at dose levels of 0.5 mL (1X), 1.5 mL (3X) or 2.5 mL (5X the maximum recommended dose) to groups of 6M and 6F kittens (52-59 days old at the start of the study). Controls were not dosed. Animals were treated on Study Day 0 and again on Study Day 28. There were no indications of toxicity, and the study was classified as acceptable].

2. The study in MRID 44850103: Fabreguettes, C. (1998) Tolerance Study by Cutaneous Application (Spot On) in Cats: Pyriproxyfen 10% Spot On for Cats: Lab Project Number: 636.29. Unpublished study prepared by Centre International de Toxicologie (C.I.T.). 254 p was previously reviewed and classified as acceptable [TXR 5002262: A formulation containing 10% pyriproxyfen as sole active was topically applied to groups of 3M and 3F 3-month old kittens for two periods of 3 consecutive days (days 1, 2, 3 and then days 19, 20, 21) at 1X (0.6 mL/treatment), 2X (1.2 mL/treatment) and 3X (1.8 mL/treatment), with doses equal to 3X, 6X and 9X over each 3-day dosing period. Although no single daily application of pyriproxyfen exceeded a 3X dosing level, a cumulative 6X exposure was achieved by the second day and a cumulative 9X exposure by the third day. The kittens used in this study were 3 months old.].
3. The material in MRID 48695018 and the companion animal (kittens) safety study in MRID 48695019 were reviewed by Summitec Corporation and DERs were prepared. TRB secondarily reviewed these DERs and made revisions as appropriate. Refer to the attached DERs for comments and conclusions.
4. TRB concludes that the companion animal safety studies cited by the registrant adequately support the use of this formulation at a dosage rate of 0.5 mL/kg on a once-a-month (or every 4 weeks) basis. However, as noted in the review for MRID 44850103, there is insufficient support for labeling this product for use in 8-week-old kittens. In MRID 44850103, the 10% Pyriproxyfen Spot On was tolerated when applied at three times the proposed dose rate over two periods of three consecutive days (days 1, 2, and 3 and then days 19, 20, and 21), but this study used 12-week-old, not 8-week-old kittens. In 48695019, deaths of three ~4-week-old kittens were considered potentially related to toxicity of the *vehicle*. It is concluded that the use of this formulation (which includes the solvent) on 12-week-old kittens is acceptable, but that an adequate margin of safety has not been demonstrated for 8-week-old kittens.
5. The registrant has proposed the statement: "Consult a veterinarian before using on medicated, debilitated or aged cats." However, the registrant has not submitted or cited data regarding the safety of this formulation (which would include the vehicle) on pregnant or nursing animals. Therefore the statement must be revised to: "Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals" as indicated in PR Notice 96-6.

DATA EVALUATION RECORD
PYRIPROXYFEN AND FIPRONIL
[EFFIPRO™ PLUS TOPICAL SOLUTION FOR CATS]

STUDY TYPE: COMPANION ANIMAL SAFETY - CATS/KITTENS;
NON-GUIDELINE DATA COMPILATION

MRIDS 486950-18

Prepared for

Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by

Summitec Corporation
9724 Kingston Pike, Suite 602
Knoxville, Tennessee 37922

Task Order No. 3-C-08

Primary Reviewer:

Donna L. Fefee, D.V.M.

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Date:

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APR 17 2012

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Quality Assurance:

Angela M. Edmonds, B.S.

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Date:

Angela M. Edmonds
APR 17 2012

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

EPA Reviewer: Byron T. Backus, Ph.D.

Signature: Byron T. Backus

Technical Review Branch, Registration Division (7505P)

Date: May 18, 2012

EPA Secondary Reviewer: Masih Hashim, Ph.D., D.V.M.

Signature: MH

Technical Review Branch, Registration Division (7505P)

Date: 5-12-20

Template version 02/06

DATA EVALUATION RECORD

STUDY TYPE: Companion Animal Safety in Cats/Kittens; Data Compilation; Non-guideline

PC CODES: 129032, 129121

DP BARCODE: 398338

TEST MATERIAL (PURITY): Effipro™ Plus Topical Solution for Cats (9.5% Fipronil and 11.5% Pyriproxyfen)

SYNONYMS: None provided.

CITATIONS: Villard, I. (2011) Summary of companion animal safety data for Effipro™ Plus Topical Solution for Cats. Isavet Biosciences, Clichy sous Bois, France. Study Number Virbac 104.15-1, December 1, 2011. MRID 48695018. Unpublished.

SPONSOR: Virbac AH, Inc., P.O. Box 162059, Fort Worth, Texas.

EXECUTIVE SUMMARY: Virbac AH has submitted a summary of the currently available companion animal safety data for the end-use product Effipro™ Plus Topical Solution for Cats (MRID 48695018). Effipro™ Plus Topical Solution for Cats is an end-use product, which contains Fipronil at the commonly used dose rate for Fipronil-only spot-on products and also contains Pyriproxyfen in order to provide a 6-week claim for flea eggs and larvae. According to the study author, the commonly used dosage for Fipronil is 50 mg/animal, and the intended dosage of Pyriproxyfen in this end-use product is 60 mg/animal. According to sample labeling (provided with MRIDs 48695010, 48695011, 48695012, 48695013, and 48695014), the product is intended for use on cats 8-weeks-old and older, and the proposed retreatment interval is ≥ 30 days.

The author of the compilation states that the many previous safety studies and more than 15 years of use have demonstrated the safety of Fipronil and Pyriproxyfen when these two active ingredients are used *separately* on cats and kittens at the dose levels proposed for Effipro™ Plus Topical Solution for Cats. The author also states that safety studies conducted with a Pyriproxyfen spot-on in young and very young kittens confirmed that Pyriproxyfen is well tolerated at the proposed dose rate and at exaggerated doses [i.e. applied at three times the proposed dose rate over two periods of three consecutive days (days 1, 2, and 3 and then days 19, 20, and 21)]. The study author concludes that existing safety data support the registration of Effipro™ Plus Topical Solution for Cats.

Data Citations:

1. Fipronil: The study author cited MRIDs 43272401, 43444904, 43863801, 43121112, and 44942009, which were stated to be OCSPP 870.7200 companion animal safety studies with

Frontline® Top Spot® for Cats (or a 0.25% Frontline® spray product) in cats. Copies of the DERs were not provided.

2. Pyriproxyfen: The study author cited MRIDs 44850103 and 48695019, which were OCSPP 870.7200 companion animal safety studies with a 10% Pyriproxyfen Spot On in kittens (12 weeks of age in MRID 44850103 and 4 weeks of age in MRID 48695019. A copy of the DER for MRID 44850103 was provided. MRID 48695019 was submitted concurrently with the data compilation study.

Reviewer's Comments: The reviewer agrees that the documentation provides support for the levels of the active ingredients that were chosen in formulating the end-use product. However, this new end-use product should be evaluated in a companion animal safety study in 8-week-old kittens in order to support that claim. While the active ingredients have been shown to be safe when dosed separately at these doses in the vehicle(s) used for Frontline® Top Spot® for Cats and the 0.25% Frontline® spray product, the combination of active ingredients and/or the vehicle used in Effipro™ Plus Topical Solution for Cats at the proposed dose level of 0.5 mL/kitten may be associated with an inadequate margin of safety.

There is insufficient support for labeling this product for use in 8-week-old kittens. In MRID 44850103, the 10% Pyriproxyfen Spot On was tolerated when applied at three times the proposed dose rate over two periods of three consecutive days (days 1, 2, and 3 and then days 19, 20, and 21), but this study used 12-week-old, not 8-week-old kittens. In 48695019, deaths of three ~4-week-old kittens were considered potentially related to toxicity of the *vehicle*. It is concluded that the use of this formulation (which includes the solvent) on 12-week-old kittens is acceptable, but that an adequate margin of safety has not been demonstrated for 8-week-old kittens.

COMPLIANCE: Signed and dated GLP and Data Confidentiality statements were provided; according to the GLP statement, because it is a "compilation document," this document is not subject to the requirements of 40 CFR Part 160.

DATA EVALUATION RECORD
PYRIPROXYFEN AND FIPRONIL
[636.29]

STUDY TYPE: COMPANION ANIMAL SAFETY STUDY- KITTENS;
NON-GUIDELINE

MRIDS 486950-19

Prepared for

Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by

Summitec Corporation
9724 Kingston Pike, Suite 602
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Task Order No. 3-C-08

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Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

EPA Reviewer: Byron T. Backus, Ph.D.

Technical Review Branch, Registration Division (7505P)

Signature: Byron T. Backus

Date: May 18, 2012

EPA Secondary Reviewer: Masih Hashim, Ph.D., D.V.M.

Technical Review Branch, Registration Division (7505P)

Signature: M. Hashim

Date: 5-20-12

Template version 02/06

DATA EVALUATION RECORD

STUDY TYPE: Companion Animal Safety Study - Kittens; Non-guideline

PC CODES: 129032, 129121

DP BARCODE: 398338

TEST MATERIAL (PURITY): 636.29 (10.31% pyriproxyfen; Batch #MS-7134)

SYNONYMS: None provided.

CITATIONS: Fabreguettes, C. (1998) Tolerance study by cutaneous application (spot-on) in young cats. Centre International de Toxicologie (C.I.T.), Miserey, Evreux, France. Study Number 15658 TSF, February 13, 1998. MRID 48695019. Unpublished.

SPONSOR: Laboratoires Virbac, 1ère Avenue - 2065 m - L.I.D., 06516 Carros, France.

EXECUTIVE SUMMARY: In a juvenile companion animal safety study (MRID 48695019), 636.29 (10.31% pyriproxyfen; Batch #MS-7134) was applied topically to groups of three male and three female approximately one-month-old kittens at 1X (0.6 mL) or 3X (1.8 mL) the intended dosing volume (doses in mg/kg bw not available) for two periods of three consecutive days (days 1, 2, and 3 and then days 19, 20, and 21) and observed for 16 days. "Excipient 636.29" (Batch No. LC 6142-1) was applied in identical manner to a control group of three male and three female animals at a dosing volume of 1.8 mL so that the animals were exposed to the inert ingredients at the maximum levels that would appear in a 3X treatment with the formulation. Replacement animals (two vehicle control females and one 3X female) were added to the study due to mortalities. These animals were treated for one period of three consecutive days (days 1, 2, and 3) and observed for 16 days. All surviving animals were sacrificed and necropsied at the end of the study with subsequent microscopic examination of the treated skin and normal skin. [Note: sacrifice and necropsy are not required under OCSPP 870.7200 or the draft version of the guideline that was in effect at the time the study was conducted.]

One 3X main-study female was sacrificed on day 10 due to observations of tremors, moderate decrease in activity, marked weight loss, moderate dehydration, and cold to the touch. One vehicle control main-study female was found dead on day 12 following observations of lateral decubitus, cold to the touch, dehydration, hypokinesia, emaciation, and difficulty breathing. An additional vehicle control main-study female was sacrificed on day 14 due to decrease in activity, dehydration, prostration, weight loss, and tremors. All showed clinical chemistry alterations and gross and microscopic findings consistent with acute renal failure due to acute tubular necrosis. Specifically, urea nitrogen, creatinine, potassium, and inorganic phosphorus levels were elevated, and kidneys grossly were pale with an irregular surface with microscopic changes that included tubular epithelial degeneration and/or necrosis, tubular dilatation with flattened epithelium, and vacuolated tubular cells,

with proteinaceous casts and/or interstitial hemorrhage and mononuclear cell aggregation in two animals. Although these deaths may be due to maternal rejection/poor feeding, or even infectious disease, they have to be considered as potentially treatment-related. Given the absence of deaths among 1X animals and the deaths in control kittens dosed with 3X vehicle, the nephrotoxicity suggests an association with an ingredient in the vehicle.

There were no treatment-related effects on hematology, clinical chemistry, and coagulation parameters, electrocardiography, or ophthalmology, and body weight did not appear to be affected in survivors.

Compared to untreated skin, treated skin of the animals of all groups had increased incidences of hyperkeratosis, inflammatory cell infiltration of the upper dermis (including granulocytes in some cases), and mast cell infiltration of the dermis, and acanthosis was only noted in treated skin. Given the similar incidences and severity across all groups, this difference may reflect a local, irritative effect of the vehicle; however, it is also possible that the difference is related to the samples being taken from different regions of the body.

Due to the occurrence of potentially treatment-related mortalities and coinciding clinical chemistry alterations and gross and microscopic changes consistent with acute renal failure due to acute tubular necrosis, it is concluded that a 3X margin of safety was not demonstrated under the conditions used in this study.

This companion animal safety study in kittens is **Unacceptable/Non-guideline**. Because dosing was at less than 5X the label recommendation and because there were only three kittens per sex per group, the study **does not satisfy** the guideline requirement for a companion animal safety study (OCSPP 870.7200) in kittens.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

- 1. Test Material:** 636.29
Description: Colorless liquid contained in plastic pipettes
Batch #: MS-7134
Purity: 10.31% pyriproxyfen; 0.02028% butylhydroxyanisol (BHA)
Compound Stability: Expiration date: May 1999; stored at room temperature, protected from light.
CAS #: Not provided.
- 2. Vehicle and/or positive control:** "Excipient 636.29" (Batch No. LC 6142-1) was used as a control. This was a colorless liquid (first receipt) or a pale yellow liquid (second receipt).

3. Test animals:

Species:	Cat
Breed:	ICO: Fec Eur (Tif)
Age/weight at study initiation:	Initial study animals: approximately 1 month/Males: 319-537 g; Females: 327-455 g Replacement animals: approximately 1.5 months/Females: 510-574 g. Age/weight of dams not reported.
Source:	Iffa Cr�do, l'Arbresle, France
Housing:	Housed with littermates and dams in stainless steel cages (acclimation)
Diet:	Complete Diet For Cats, Expanded Pellets (U.A.R. Villemoisson-sur-Orge, France), <i>ad libitum</i>
Water:	<i>Ad libitum</i> tap water
Environmental conditions:	Temperature: 20�5� C. Humidity: 50�20% Air changes: ~12 per hour Photoperiod: 12 hrs light/12 hrs dark
Acclimation period:	Seven days

B. STUDY DESIGN:

1. In life dates: Start: September 9, 1997; End: October 16, 1997.
2. Animal assignment: Study design is given in Table 1. Healthy animals were selected for inclusion in the study according to the results of pretreatment clinical examinations, hematology, and clinical chemistry. The original animals were allocated by a random procedure to groups 1 through 3 by litters and according to body weight so that the average body weight of each group was similar. It was unclear whether this meant that all of the animals in a given group were from the same litter. Following the death or moribund sacrifices of three kittens (during days 10-14), three replacement animals were assigned and treated at the same time as the initial (main study) animals were in their second treatment period.

Table 1. Study design ^a					
Test Group	Dosing volume (mL/animal)	Schedule ^b		Number assigned	
		Treated	Killed	Males	Females
Main Study					
1. Vehicle control (3X)	1.8	Days 1, 2, 3, 19, 20, and 21	Day 37	3	3
2. 1X	0.6			3	3
3. 3X	1.8			3	3
Replacements					
4. Vehicle control (3X)	1.8	Days 1, 2, and 3	Day 20	0	2
5. 3X	1.8			0	1

^a Data taken from pp. 10, 14, and 23-24, MRID 48695019.

^b Days 1, 2, and 3 for the replacement animals were the same calendar days as days 19, 20, and 21 for the main study animals.

3. Dose selection rationale: The dose levels were selected by the sponsor. According to the study author, the study design was intended to comply with EPA's draft OPPTS 870.7200 guideline [now OCSPP 870.7200] and E.E.C. Recommendation No. 92/18/E.E.C., March 20, 1992. The intended therapeutic dose is 0.6 mL/cat, and the dose levels chosen for the study are 1X and 3X

the therapeutic dose level. According to sample labeling (provided with MRIDs 48695010, 48695011, 48695012, 48695013, and 48695014), the proposed retreatment interval is ≥ 30 days.

4. **Treatment:** The control or test material, as appropriate, was applied topically to the skin at the base of the skull after first parting the hair at the application site. The control substance was applied using a 2-mL disposable syringe, and the test material was applied using either one or three 0.6-mL pipettes for the 1X and 3X animals, respectively. Treatments were applied once per day, at approximately the same time each day, on days 1, 2, 3, 19, 20, and 21 for the main study animals and on days 1, 2, and 3 for the complementary (replacement) animals. [Days 19, 20, and 21 for the main study animals were the same calendar days as days 1, 2, and 3 for the complementary animals, i.e. September 27, 28, and 29, 1997.]
5. **Statistics:** Body weight, electrocardiography, hematology, and blood biochemistry data were analyzed. The Kolmogorov-Lilliefors test was used to evaluate whether the data were normally distributed. For comparison of three or more groups, data with a normal distribution were assessed for homogeneity of the variance between groups using Bartlett's test and then further analyzed using either Dunnett's test or Dunn's test for homogeneous or heterogeneous variances, respectively. For comparison of two groups, the data were analyzed using Fisher's test followed by Student's test if the variances were homogeneous or the Mann-Whitney U test if the variances were heterogeneous. Data that were not normally distributed were re-evaluated following logarithmic transformation. If transformation resulted in a normal distribution, the data were evaluated as detailed above. Otherwise the untransformed data were analyzed using Dunn's test.

C. **METHODS:**

1. **Observations:** The animals were observed cageside at least twice daily for mortality and moribundity. Clinical signs were observed and recorded at least once daily, at approximately the same time each day. On treatment days, the kittens were kept apart from the mother for approximately one hour after treatment in order to prevent the mother from licking the kittens immediately after the test material was applied, and additional observations of clinical signs were made once per hour for four hours following treatment. Licking between the kittens and licking of the kittens by the mother were also observed and recorded on treatment days.
2. **Body weight:** The kittens were weighed once prior to allocation, on the first day of treatment, and weekly thereafter.
3. **Food consumption:** Food consumption was not measured.
4. **Hematology and clinical chemistry:** Pre-treatment, day 4, and day 22 (main study only), blood for hematology, clinical chemistry, and coagulation evaluation was collected from the jugular or cephalic vein without anesthesia or prior fasting. Complete evaluations were also conducted on the animals that died or were sacrificed ahead of schedule. The CHECKED (X) parameters were examined. Additional sampling for urea and creatinine evaluation was done on day 10 for the 3X main-study and replacement animals and on day 28 for the surviving vehicle control and 3X main-study animals.

a. Hematology:

X	Hematocrit (HCT)*	X	Leukocyte differential count*
X	Hemoglobin (HGB)*	X	Mean corpuscular HGB (MCH)*
X	Leukocyte count (WBC)*	X	Mean corpusc. HGB conc.(MCHC)*
X	Erythrocyte count (RBC)*	X	Mean corpusc. volume (MCV)*
X	Platelet count	X ^a	Reticulocyte count
	Blood clotting measurements		Morphology (blood smear)
X	(Thromboplastin time)*	X	Fibrinogen
	(Clotting time)		
X	(Prothrombin time)*		

* Recommended for companion animals safety evaluation based on OCSPP 870.7200.

^a Smears were prepared, but reticulocytes were not counted if anemia was not present.

b. Clinical Chemistry:

	ELECTROLYTES		OTHER
X	Calcium*	X	Albumin*
X	Chloride*	X	Creatinine*
	Magnesium	X	Urea nitrogen (BUN)*
X	Phosphorus*	X	Cholesterol
X	Potassium*		Globulins*
X	Sodium*	X	Glucose*
	ENZYMES	X	Total bilirubin*
X	Alkaline phosphatase (ALK)*	X ^a	Direct bilirubin*
	Cholinesterase (ChE)		Indirect bilirubin
	Creatine phosphokinase	X	Total protein (TP)*
	Lactic acid dehydrogenase (LDH)	X	Triglycerides
X	Alanine aminotransferase (ALT/also SGPT)*		Scrum protein electrophoresis
X	Aspartate aminotransferase (AST/also SGOT)*	X	Albumin/globulin ratio
	Sorbitol dehydrogenase		Bicarbonate
	Gamma glutamyl transferase (GGT)		
	Glutamate dehydrogenase		
	Amylase		

* Recommended for a companion animal safety evaluation based on OCSPP 870.7200.

^a Only determined if total bilirubin was greater than 20 µmol/L.

- 5. Electrocardiography:** All of the kittens were given 3-lead electrocardiographic examinations pre-treatment and on days 18 and 37 (main study) or on day 19 (replacement animals). The heart rate and P-Q interval, Q-T interval, and QRS complex were measured on lead II.
- 6. Ophthalmology:** All of the kittens were given eye examinations pre-treatment and on days 18 and 37 (main study) or on day 19 (replacement animals). Pupils were dilated using Mydriaticum® (tropicamide) and indirect ophthalmoscopy was used to examine the appendages, optic media, and fundus. Pupillary light reflexes and blink reflexes were evaluated as appropriate to the age of the animals.
- 7. Sacrifice and pathology:** On day 38 (main study) or day 20 (replacement animals), the surviving animals were euthanized via exsanguination under tiletamine/zolazepam/thiopental sodium

anesthesia, and moribund animals were killed in this same manner. All animals were subjected to complete necropsy, and the indicated (X) organs or tissues were collected and preserved in neutral buffered formalin, Davidson's fixative (eyes with optic nerve), or Bouin's fluid (testes) for potential future histopathological evaluation. Treated and untreated skin from all animals and all macroscopic lesions in the animals that died or were sacrificed ahead of schedule were examined microscopically.

X	DIGESTIVE SYSTEM	X	CARDIOVASC./HEMAT.	X	NEUROLOGIC
X	Tongue		Aorta	X	Brain
X	Salivary glands	X	Heart	X	Peripheral nerve (sciatic)
X	Esophagus	X	Bone marrow	X	Spinal cord
X	Stomach	X	Lymph nodes	X	Pituitary
X	Duodenum	X	Spleen	X	Eyes (optic nerve)
X	Jejunum	X	Thymus	X	GLANDULAR
X	Ileum			X	Adrenal gland
X	Cecum	X	UROGENITAL	X	Parathyroid
X	Colon	X	Kidneys	X	Thyroid
X	Rectum	X	Urinary bladder		
X	Liver		Ureters	X	OTHER
X	Gall bladder	X	Testes	X	Bone
X	Pancreas	X	Epididymides	X	Joint
X	RESPIRATORY	X	Prostate	X	Skin, both treated and untreated
X	Trachea		Seminal vesicles	X	Skeletal muscle
X	Lung	X	Ovaries	X	Mammary gland
	Nose		Oviduct		Peyer's patch
	Pharynx	X	Uterus with cervix	X	All gross lesions and masses
	Larynx	X	Vagina		

II. RESULTS

A. **EXPOSURE:** The doses to the animals in mg/kg bw cannot be determined because dosages were in mL, while the provided certificate of analysis reported active ingredient content on a g/100 g basis, and the density or specific gravity of the test material was not provided.

B. **OBSERVATIONS:**

1. **Mortality and clinical signs:** One 3X main-study female was sacrificed on day 10 due to observations of tremors, moderate decrease in activity, marked weight loss, moderate dehydration, and cold to the touch (all recorded on day 10). One vehicle control main-study female was found dead on day 12 following observations of lateral decubitus, cold to the touch, dehydration, hypokinesia, emaciation, and difficulty breathing (all recorded on day 12). An additional vehicle control main-study female was sacrificed on day 14 due to observations of decrease in activity, dehydration, prostration, weight loss, and tremors (all recorded on day 14). No other abnormal clinical signs were recorded; all of the remaining animals were designated as "no clinical history" for days 1-38 (main study) or 1-20 (replacements).
2. **Licking:** No licking between the kittens was observed. One vehicle control main-study male and one 3X main-study male were observed being licked by their mothers on day 1. Licking

observations were recorded for the decedent and prematurely sacrificed main study females on days 19, 20, and 21 (as no licking by the mother or between the kittens in all cases). It is assumed that these notations referred to the replacement animals.

3. **Cosmetic effects and migration or runoff of the test or control article:** There was no evaluation of cosmetic effects or the migration or runoff of the test or control articles.

- C. **BODY WEIGHT AND WEIGHT GAIN:** Selected body weight data are given in Table 2. There were no clear treatment-related effects on body weight or body weight gain. The 3X main-study female killed on day 10, the vehicle control main-study female that died on day 12, and the vehicle control main-study female killed on day 14 all lost weight between day 8 and the day of death (54, 53, and 65 g, respectively). Otherwise, the individual kittens generally gained weight between successive measurements during the treatment interval. The exception was one of the vehicle control replacement females that maintained the same body weight of 794 g between days 15 and 19.

TABLE 2: Body weight data (g) ^a				
Parameter/ Study day or interval		Dosage		
		Vehicle control	1X	3X
Main Study Males				
Body Weight:	Day 1	368±8.7	337±16.4	476±53.6
	Day 8	420±51.6	377±16.5	501±53.8
	Day 19	623±77.9	555±35.2	749±69.6
	Day 26	760±81.1	678±35.3	831±70.3
	Day 37	951±72.3	888±28.2	1103±70.6
BW gain ^b :	Days 1-37	583	551	627
Main Study Females				
Body Weight:	Day 1	357±27.4	431±24.5	430±38.5
	Day 8	370±32.0	455±21.8	442±89.1
	Day 19	644	630±50.1	711±77.1
	Day 26	749	748±43.1	830±87.0
	Day 37	938	956±68.6	1082±100.4
BW gain ^b :	Days 1-37	581	525	652
Replacement Females				
Body Weight:	Day 1	518±11.3	N/a	574
	Day 8	635±3.5	N/a	628
	Day 19	789±7.8	N/a	879
BW gain ^b :	Days 1-19	271	N/a	305

^a Data taken from pp. 32-33 and 104-105, MRID 48695019. Values are Mean ± Standard Deviation (where available), with n=3 for all main study groups initially, n=1, 3, 2 for main study females after day 8, and n=2, 0, and 1 for replacement females (ascending group order).

^b Calculated by reviewer using group mean body weight values; not analyzed statistically.

D. BLOOD ANALYSES:

1. **Hematology and coagulation:** The study author stated that all values were within the physiological range and/or the historical background range for this strain and species housed at this laboratory, but historical control values were not provided. Statistically significant differences were found between groups for some of the parameters at some of the time points, but none were considered treatment-related due to the absence of a dose response, the occurrence of the difference prior to initiation of treatment, and/or small magnitude.
2. **Clinical Chemistry:** Results of clinical chemistry evaluations on the day of death or sacrifice of the 3X main-study female killed on day 10, the vehicle control main-study female that died on day 12, and the vehicle control main-study female killed on day 14 all showed increased urea nitrogen, creatinine, potassium, and inorganic phosphorus, i.e. finding consistent with acute renal failure.

Statistically significant differences were found between groups for some of the parameters at some of the routine, scheduled measurement intervals, but none were considered treatment-related due to the absence of a dose response, the occurrence of the difference prior to initiation of treatment, and/or small magnitude. The study author noted a pattern of change in which the mean urea nitrogen levels (BUN) of the vehicle control and 3X main-study animals of both sexes increased over time. Given that there was no co-occurring change in creatinine concentration and that none of the individual BUN values exceeded 35 mg/dL, these changes are not considered toxicologically significant.

- E. ELECTROCARDIOGRAPHY:** None of the evaluated parameters were affected by treatment.

- F. OPHTHALMOLOGY:** On day 37, one 1X main-study female had small reddish spots on the tapetum lucidum of both eyes, with some of the spots being along blood vessels. This finding was not seen during the previous examinations and is of unknown significance but is not considered treatment-related because it occurred at only a single incidence and without a dose response. Slight hypopigmentation of the tapetum lucidum was noted in several kittens during the pre-treatment examination.

G. SACRIFICE AND PATHOLOGY:

1. **Gross pathology:** Gross findings in the animals that died or were sacrificed moribund included irregular surface and pallor of the kidneys in all three and blackish stomach contents or blackish deposits in the stomachs of the two vehicle control animals. The only other abnormal finding was a serous ovarian cyst in one of the replacement vehicle control females, which was not considered treatment-related.
2. **Microscopic pathology:** Histopathological correlates to the gross kidney findings in the two vehicle control and one 3X main study females that died or were sacrificed moribund included moderate to severe tubular epithelial degeneration and/or necrosis, tubular dilatation together with flattened epithelium, and vacuolated tubular cells in both kidneys in all three animals, proteinaceous casts in one vehicle control and the 3X animal, and interstitial hemorrhage and mononuclear cell aggregation in the 3X animal. There were no histopathological correlates to the gross stomach findings.

The skin histopathology observations are given in Table 3. Compared to untreated skin, treated skin of the animals of all groups had increased incidences of hyperkeratosis, inflammatory cell infiltration of the upper dermis (including granulocytes in some cases), and mast cell infiltration of the dermis, and acanthosis was only noted in treated skin. Given the similar incidences and severity across all groups, this difference may reflect a local, irritative effect of the vehicle; however, it is also possible that the difference is related to the samples being taken from different regions of the body.

TABLE 3: Skin histopathology (incidence) ^a						
Observation	Dosage					
	Vehicle control		1X		3X	
	Males	Females	Males	Females	Males	Females
Untreated skin						
Number examined ^b	3	5	3	3	3	4
Hyperkeratosis	1	--	2	--	--	1
Inflammatory cell infiltration, upper dermis	--	1	--	--	1	1
Mast cell infiltration, dermis	--	--	--	--	--	1
Erosion	1	--	--	--	--	--
Treated skin						
Number examined ^b	3	5	3	3	3	4
Hyperkeratosis	2	2	1	2	2	2
Acanthosis	--	1	--	--	1	1
Inflammatory cell infiltration, upper dermis	1	1	2	1	3	1
Mast cell infiltration, dermis	3	3	3	3	3	3
Erosion	--	--	--	1	--	--

^a Data taken from p. 73, MRID 48695019.

^b Includes animals that died/were euthanized on days 12-14, animals that underwent two 3-day treatment intervals and were euthanized on day 37, and animals that underwent a single 3-day treatment interval and were euthanized on day 20.

III. DISCUSSION and CONCLUSIONS

A. INVESTIGATORS' CONCLUSIONS: The study author concluded that daily administration of the test material to ~30-day-old and ~45-day kittens by cutaneous (spot-on) application at dose levels of 0.6 or 1.8 mL/animal was well tolerated. The study author stated that the only effects were minor microscopic changes in the skin of treated and control animals that were possibly due to a minimal irritative effect of the excipient. The study author set a NOAEL of 1.8 mL/animal for 636.29 by cutaneous application under the conditions of this study.

The study author attributed the deaths and moribund sacrifices in the vehicle control and 3X females and the findings in these animals to "unspecific decline of physical condition, possibly due to poor quality of feeding or to rejection by the mother, leading to dehydration and electrolyte imbalance." In particular, the study author attributed the histopathological findings in these animals to their "poor physical condition."

B. REVIEWER'S COMMENTS:

The study deviated from OCSPP 870.7200 and the draft version of the guideline that was in effect at the time the study was conducted in using only three animals/sex/dose and using a maximum dose of only 3X the label recommendation rather than 5X. For these reasons, the study cannot be used to satisfy a guideline requirement for a companion animal safety study in kittens. However the results of this study can be used to provide additional, supplemental information.

The animals that died or were sacrificed moribund warrant further discussion. These deaths/sacrifices occurred within a 5-day time frame, with the animals exhibiting similar clinical signs, and all three animals had clinical chemistry alterations and gross and microscopic findings consistent with acute renal failure due to acute tubular necrosis. At 4-6 weeks of age, kittens are able to begin eating solid food, and it is unfortunate that the testing laboratory did not provide moist food (even moistened pellets) to facilitate the weaning process; however, the reviewer believes that the facility personnel would have noticed rejection by the mother or "poor feeding" early enough to intervene in advance of moribundity. The reviewer agrees that acute tubular necrosis with subsequent renal failure can result from renal ischemia due to hypovolemia, dehydration, hypotension, or shock. However, given the brief duration and rapid course of the clinical signs, and in the absence of urinalysis, treatment-related nephrotoxicity must also be considered a possibility, along with infectious disease. Given the absence of deaths among 1X animals and the deaths in control kittens dosed with 3X vehicle, the nephrotoxicity suggests an association with an ingredient in the vehicle.

The reviewer agrees that the application of the test material at 1X and 3X the recommended dose and application of the vehicle control at 3X times the recommended dose may have resulted in minor microscopic changes in the skin that were consistent with irritation.

Due to the occurrence of potentially treatment-related mortalities and coinciding clinical chemistry alterations and gross and microscopic changes consistent with acute renal failure due to acute tubular necrosis, it is concluded that a 3X margin of safety was not demonstrated under the conditions used in this study.

C. STUDY DEFICIENCIES: The following deficiencies and/or significant deviations from the 870.7200 Guidelines were identified:

- Group size was only three animals/sex/dose.
- The maximum dose was 3X the label recommendation rather than 5X.
- Sacrifice and necropsy were conducted unnecessarily at the end of the study.

1. **DP BARCODE:** 398338
2. **PC CODES:** 129032 (Pyriproxyfen: 11.5%); 129121 (Fipronil: 9.5%)
3. **CURRENT DATE:** May 18, 2012
4. **TEST MATERIAL:** [for the study in MRID 48695019: 636.29 (10.31% pyriproxyfen; Batch #MS-7134)]

Study/Species/Lab Study # / Date	MRID	Results	Tox. Cat.	Core Grade
Companion animal safety/one-month-old kittens/Laboratoires Virbac/Study No. 15658 TSF/Feb. 13, 1998	48695019	636.29 was topically applied to groups of 3M & 3F ~1 month-old kittens at 1X (0.6 mL) or 3X (1.8 mL) for two periods of 3 consecutive days (1,2,3 and then days 19, 20, 21). "Excipient 636.29" was applied in an identical manner to a control group of 3M & 3F at a dosing volume of 1.8 mL. Replacement animals (2 vehicle control females and one 3X female) were added to the study due to mortalities; these animals were treated for one period of 3 consecutive days (days 1, 2 & 3) and observed for 16 days. One 3X female was sacrificed on day 10 due to tremors, moderate activity decrease, marked weight loss, moderate dehydration and hypothermia. One vehicle control female was found dead on day 12, and an additional vehicle control female was sacrificed on day 14. Signs in these kittens included dehydration, weight loss/emaciation, and one had difficulty in breathing. Clinical chemistry alterations & gross and microscopic findings were consistent with acute renal failure due to acute tubular necrosis. This nephrotoxicity suggests an association with an ingredient in the vehicle. It is concluded that a 3X margin of safety was not demonstrated in this study. Study is classified as unacceptable/non-guideline.	n/a	U
Companion animal safety/compilation of previously submitted studies	48695018	Cites previously reviewed domestic animal (cat & kitten) studies in MRIDs 43272401, 43444904, 43863801, 43121112 and 44942009, as well as 44850103 and 48695019.	n/a	S

Core Grade Key: A = Acceptable, S = Supplementary, U = Unacceptable, W = Waived



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

BARCODE No.: 398333; FILE SYMBOL No.: 2382-RII;
PRODUCT NAME: Effipro Plus Topical Solution for Cats; DECISION No.: 458840;
PC Code(s): 129121 & 120932; Action Code: R310; FOOD Use: No

DATE: May 9, 2012

SUBJECT: Product Name: Effipro Plus Topical Solution for Cats

FROM: Akiva Abramovitch, Ph.D.
Technical Review Branch / RD (7505P)

THROUGH: Shyam Mathur, Ph.D.
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

TO: Bonaventure Akinlosotu/Richard Gebken, PM 10
Insecticide Branch/ RD (7505C)

Company Name: Virbac
Formulation Type: Spot-On Solution

INTRODUCTION:

The applicant has submitted an application for registration of a new end use product. In support of the registration application, the registrant has submitted product chemistry data corresponding to guideline 830 series, group A & group B (MRIDs 486950-01 through -09). The CSF of the basic formulation (dated 10/15/2011) was submitted along with the product label. TRB has been asked to determine the acceptability of the product chemistry data and the proposed basic CSF dated October 15, 2011.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient: Fipronil (9.5%) and Pyriproxyfen (11.5%).
2. Has the registrant claimed substantial similarity to a registered product?

[X] Yes; [] No; if yes give the registration number of the cited product. EPA Reg. No. 2382-186

3. All the source materials for the active ingredients are derived from the registered sources:

[X] Yes; [] No. [REDACTED] added to the CSF.

BARCODE No.: 398333;

PRODUCT NAME: Effipro Plus Topical Solution for Cats;

PC Code(s): 129121& 120932; **Action Code:** R310;

FILE SYMBOL No.: 2382-R11;

DECISION No.: 458840;

FOOD Use: No

4. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled uses: ☒ Yes; ☐ No.

5. Confidential Statement of Formula(s):

☒ Basic Dated: October 15, 2011;

6. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concur with product label (PR Notice 91-2).

☒ Yes, if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)?

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA;

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid equivalent: ☐ Yes ☒ NA; {name} acid equivalent = xx %

b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☒ No ☐ NA

Methanol at > 4%: ☐ Yes ☒ No ☐ NA

Sodium nitrate/Sodium nitrite ☐ Yes ☒ No ☐ NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes, ☐ No, ☒ NA, if not, explain below:

d. Label requires an additional Storage and Disposal statement:

☐ Yes ☒ No

BARCODE No.: 398333;

FILE SYMBOL No.: 2382-RII;

PRODUCT NAME: Effipro Plus Topical Solution for Cats;

DECISION No.: 458840;

PC Code(s): 129121& 120932; **Action Code:** R310;

FOOD Use: No

7. Group A: Product Chemistry Data

TRB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	486950-01
830.1600	Description of materials used to produce the product		X		A	486950-01
830.1650	Description of formulation process		X		A	486950-01
830.1670	Discussion on the formation of impurities		X		A	486950-01
830.1700	Preliminary analysis		X		A	486950-02 and 03
830.1750	Certified limits (158.350)	Standard certified Limits	X		A	486950-01
		Proposed Limits			NA	
		Justification for wider limits			NA	
830.1800	Enforcement analytical method		X		A (HPLC method)	486950-02 and - 03

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable

BARCODE No.: 398333;

PRODUCT NAME: Effipro Plus Topical Solution for Cats;

PC Code(s): 129121& 120932; **Action Code:** R310;

8. Group B:

FILE SYMBOL No.: 2382-RII;

DECISION No.: 458840;

FOOD Use: No

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Colorless liquid with sweet odor	A	486950-04
830.6315	Flammability	94.3°C flashpoint	A	486950-06
830.6316	Explodability	NA, not considered to be potentially explosive	A	486950-02
830.7000	pH	6.0 1% solution at 23 C	A	486950-07
830.7300	Density (units)	1.0463 g/cm ³	A	486950-09

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request,
NA = Not applicable, I = In progress, U = Upgradeable

CONCLUSIONS:

TRB has reviewed the CSF(s) and product chemistry data for the proposed end use product and has concluded:

1. The proposed CSF for the basic formulation dated October 15, 2011 is acceptable
2. The data submitted corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product), 830.1650 (description of formulation process), 830.1670 (discussion on the formation of impurity), 830.1750 (certified limits), and 830.1800 (enforcement analytical method) are acceptable.
3. The product chemistry data submitted corresponding to guidelines 830.6302 (color), 830.6303 (physical state), 830.6304 (odor), 830.6314 (oxidation/reduction), 830.6315 (flammability), 830.6316 (explodability), 830.7000 (pH), 830.7100 (viscosity), and 830.7300 (density) are acceptable.
4. The storage stability (guideline 830.6317) and corrosion characteristics (guideline 830.6320) studies were not submitted. These physical/chemical properties are required and it is recommended that observations should be made at 0, 3, 6, 9, and 12 month intervals.
5. The proposed label was screened as it pertains to the product chemistry requirements. Review of the proposed label and uses are the purview of the RM team.

Decision Information for 2382-RII

Decision Seq: 458840		Action Code: R310, NEW PRODUCT, NON-FAST TRACK (INCLUDES REVIEWS O ...		Decision Status	
FFS Start Date: 06-Jan-2012		Tentative Ind: No		Tracking	
Due Date: 06-Jul-2012		75-Day Due Date:		Create Resubmission	
OPP Target Due Dt:		21-Day Screen Dt: 06-Jan-2012		FFS Letters	
Negotiated Due Dt:		Start/Stop Clock		Waiver Documentation	
Registrant Response Due Date:		Days Elapsed:		Action Code History	
Current Status: PENDING (19-Dec-2011)				Secondary Decision	

Decision Comments	Payment	Unmatched Payments	75 Day Letters
Meetings & Milestones	FFS Information	FFS Negotiated Due Dates	OPP Target Due Date
Decision Ownership	Receipts	Data Package	Reduced Risk

Receipts	Staff Member	Reg/OCI Number	Submission Due Dt	Response
S: 008625	Akinosotu Bonaventure	2382 RII	06-Jul-2012	PENDING
New Product Application				

< 101 >

Viewing Record 1 of 1

Received 1/31/2012

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 12-16-11 3/23/09

Experts In-Processing Signature: B. [Signature] Date 12-20-11 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>2382 - RII</u>		EPA Receipt Date: <u>12-16-11</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			<input checked="" type="checkbox"/>		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			<input checked="" type="checkbox"/>		
	a) All inerts (link to http://www.epa.gov/oppr001/inerts/), including fragrances, approved for the proposed uses (see Footnote A) <u>NON-FOOD</u>	yes	no			
		<input checked="" type="checkbox"/>				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			<input checked="" type="checkbox"/>		
	Certificate and data matrix consistent			<input checked="" type="checkbox"/>		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)			<input checked="" type="checkbox"/>		
	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			<input checked="" type="checkbox"/>		
5	a) Selective Method (Fee category experts use)	yes	no			
		<input checked="" type="checkbox"/>				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			<input checked="" type="checkbox"/>		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.	X		
	a) List study (or studies) not included with application			

Comments: 12/20 - JACKET ARRIVES, BUT NO STUDIES ARE IN ESTUDIES. AA 12/20

12/21 - CALL MADE - NO ANSWER. EMAIL SENT REGARDING
MISSING STUDIES

* DATA FOUND (INACCURATE RECORD) - PASSED 86-S REVIEW. AA 12/30/11

MRID 486950

Inerts OK - NON FOOD USE PRODUCT.

AA 12/20/11

/r/v

* N/A - Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses even if a **product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/opphbpd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R30I or A53I. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

R 310

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGA). Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or NO (circle one)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition	X					
830.1600	Description of materials used to produce the product	X					
830.1650	Description of formulation process	X					
830.1670	Discussion on the formation of impurities	X					
830.1700	Preliminary analysis	X					
830.1750	Certified limits (158.345)	X					
830.1800	Enforcement analytical method	X					

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.6302	Color	X					
830.6303	Physical State	X					
830.6304	Odor	X					
830.6313	Stability to normal and elevated temperatures metal and metal ions						
830.6314	Oxidation/Reduction (Chemical incompatibility)	X					
830.6315	Flammability	X					
830.6316	Explosibility	X					
830.6317	Storage stability	X					
830.6319	Miscibility	X					
830.6320	Corrosion Characteristics	X					
830.6321	Dielectric Breakdown Voltage	X					
830.7000	pH	X					
830.7050	UV/ Visible Absorption						
830.7100	Viscosity	X					
830.7200	Melting Point						
830.7220	Boiling Point						
830.7300	Density	X					
830.7370	Dissociation Constant						
830.7550	Partition Coefficient						
830.7840	Water Solubility						
830.7950	Vapor Pressure						

Grayed out = data not required

Fee for Service

JK
{9086255~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies? ☐ Fee Waiver?
☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☐ RD

Risk Mgr. **10**

Receipt No.

S- **908625**

EPA File Symbol/Reg. No.

2382-R11

Pin-Punch Date:

12/16/2011

☐ This item is NOT subject to FFS action.

Action Code:

Requested: **R310**

Granted: **R310**

Amount Due: \$ **4807**

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: S. Hill

Date: 12/19/11

Remarks:

Explore Registrations					
Reg Number:	2382-R11	Reg Type:	Product Registration - Section 3	Status:	Under Review (19-Dec-2011)
Name:	EFFIPRO PLUS TOPICAL SOLUTION FOR CATS			View Registration Details	
(No New Receipts)					
S	Submission Type	OPP Rec'd Date	Resubmission	Description	
<div style="display: flex;"> <div style="flex: 1;"> <p>...Decisions...</p> <ul style="list-style-type: none"> Data Requirements D: Pending; 458840; 2382-R11; R310; NEW PROD 75-Day Letters S: 908625 12/16/2011; New Registration </div> <div style="flex: 2;"> <p>S: 908625 Reg #: 2382-R11</p> <p>Submission Type: New Registration</p> <p>Resubmission? <input type="radio"/> Yes <input checked="" type="radio"/> No E-Sub #: </p> <p>Decision #: 458840; R310; NEW PRODUCT; NON-FAST TRACK (INCLUDES</p> <p>Submitter Company: VIRBAC AH, INC.</p> <p>Application Date: 16-Dec-2011</p> <p>OPP Received Date: 16-Dec-2011 Date Sent to Risk manager: 19-Dec-2011</p> <p>Studies Included? <input type="radio"/> Yes <input checked="" type="radio"/> No Fast Track? <input type="radio"/> Yes <input checked="" type="radio"/> No</p> <p>Form A Signed? <input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> None Date: </p> <p>Form B Signed? <input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> None Date: </p> <p>Reviewer: Akinlosotu, Bonaventure</p> <p>Received DT: Editable Due DT: </p> <p>Submission Due DT: 06-Jul-2012 Response: D, 16-Dec-2011</p> <p>Priority Weight: Priority Points: </p> <p>Comments: New Product Application</p> </div> </div>					

2 prod's
2382-R11
R10

9.5% Fipronil
11.5% Pyriproxyfen) Spot-on for cats.

- Similar to 2382-186 (except it contains IGR pyriproxyfen)
- Selective Citation:

-Submits prod chem, Acute tox, Efficacy, CAS; Cites CRP data

- Prod Chem
- Acute Tox/PL
- Tox/CAS
- Efficacy
- CRP

{Master Label}

Virbac's Master Label

Date December 13, 2011 Version US-7 EPA Reg. No. 2382-XXX
Fipronil + Pyriproxyfen Topical Solution for Cats

Virbac

EFFIPRO[®] PLUS TOPICAL SOLUTION FOR CATS

FOR USE ONLY ON CATS AND KITTENS 8 WEEKS OLD OR OLDER

ACTIVE INGREDIENTS:

Fipronil 9.5%
Pyriproxyfen 11.5%

OTHER INGREDIENTS: 79.0%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ ENTIRE LABEL BEFORE EACH USE

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Possible temporary irritation may occur at the site where EFFIPRO[®] PLUS Topical Solution for Cats was applied. Contact a veterinarian immediately if signs become persistent or become more severe during the first few days following application. If an unusual reaction is observed following initial application, a veterinarian should be consulted before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged cats.

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents.	

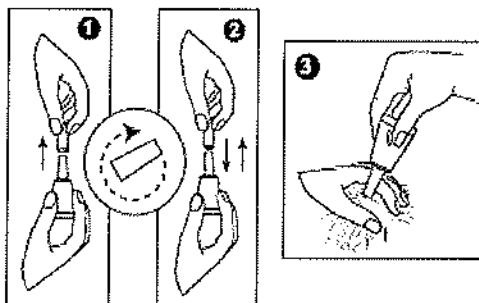
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

For killing fleas, flea eggs, flea larvae, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that which) may transmit [carry] Lyme disease), mosquitoes, and chewing lice; apply to CATS or KITTENS [8 weeks old or older] as follows:

APPLICATION DIRECTIONS

1. Remove one applicator from packaging.
Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator tip.
Push cap down to break seal.
Remove cap prior to treatment application.
3. Part cat's hair between shoulder blades until skin is visible.
Place applicator tip directly against exposed skin.
Deposit entire contents by squeezing the applicator at a single site on cat's skin.
Ensure that EFFIPRO® PLUS Topical Solution for Cats is not applied superficially on cat's hair.



FREQUENCY OF APPLICATION

EFFIPRO® PLUS Topical Solution for Cats will kill fleas, ticks and chewing lice when applied monthly.

Fleas: EFFIPRO® PLUS Topical Solution for Cats can control fleas for up to six weeks. Apply monthly if your cat has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely. EFFIPRO® PLUS Topical Solution for Cats can control flea eggs (and larvae) for up to three months (90 days).

Ticks: EFFIPRO® PLUS Topical Solution for Cats can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.

Chewing Lice: EFFIPRO® PLUS can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Cats can kill mosquitoes within 24 hours (for up to 14 days), and within 48 hours (for up to 28 days).

Notes: Wait at least 30 days before re-application of EFFIPRO® PLUS Topical Solution for Cats. Avoid contact with treated area until dry.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE /CONTAINER DISPOSAL: If empty: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND DISCLAIMER

To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this product not in accordance with directions. Buyer and user assume all risks of use and handling of this material when such use and handling are contrary to label instructions. To the extent consistent with applicable law, any damage arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.

Net Contents: 1, 3, 6 or 36 single-dose applicator(s) per package. Each applicator contains 0.017 fl oz (0.5 mL) of solution.

(Detachable) calendar (monthly application) reminder stickers with (illustration of cat or kitten).

EPA Reg. No. 2382-XXX

EPA Est. No. 2382-XXX

VIRBAC AH, INC.
PO BOX 162059
FORT WORTH, TX 76161
1-800-338-3659

Made in France
EFFIPRO® is a registered trademark of Virbac S.A. in the United States.
Questions or comments?
Call: 1-800-338-3659

{Text for Front Panel, Back Panel and Side Panel}

See package insert(s) for directions for use and frequency of application
Open resealable label for directions for use
Open resealable label for directions for use and storage and disposal
See back panel for additional precautionary statements
See package insert(s) for frequency of application
See enclosed insert(s) for directions for use and storage and disposal
See enclosed insert(s) for directions for use

Use only on cats
For Use on Cats only
Only for cats and kittens 8 weeks old or older
(1, 3, 6 or 36) applicator(s) 0.017 fl oz (0.5 ml)

Photograph of cat or kitten

Lift here to open (LIFT HERE TO OPEN)

{Text for Foil of Blister package}

Virbac
EFFIPRO® PLUS Topical Solution for Cats
Only for use on cats 0.017 fl oz (0.5 ml)
Contains fipronil (9.5%) and pyriproxyfen (11.5%)
KEEP OUT OF REACH OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-XXX

{Text for Applicator Tube}

Virbac
EFFIPRO® PLUS
Topical Solution for Cats
Only for use on cats
0.017 fl oz (0.5 mL)
Contains fipronil (9.5%) and pyriproxyfen (11.5%)
KEEP OUT OF REACH
OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-XXX

MARKETING CLAIMS

[Multiple infestations]

- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea larvae, ticks, mosquitoes and chewing lice (for CATS and KITTENS 8 weeks old or older).
- For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing lice (for CATS and KITTENS 8 weeks old or older).
- EFFIPRO® PLUS Topical Solution for Cats contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice (on cats) (8 weeks old or older).
- EFFIPRO® PLUS Topical Solution for Cats contains the active ingredient pyriproxyfen, which controls reinfestation caused by flea eggs, flea larvae (on cats) (8 weeks old or older).
- For killing fleas, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks, (which/that may carry (transmit) Lyme disease), mosquitoes and chewing lice; apply to CATS or KITTENS (8 weeks old or older) as follows: (followed by application directions).
- Persistent flea and tick efficacy for up to one month (4 weeks) (30 days)
- Prevents flea and tick (re-)infestation for up to one month (4 weeks)
- Effective monthly application for (on) fleas and ticks

- Effective monthly application for cats (and kittens) against fleas and ticks
 - Kills fleas and ticks for up to one month (4 weeks)
 - Kills fleas, ticks, mosquitoes and chewing lice
 - Kills fleas, ticks, mosquitoes and lice
 - Kills, fleas, flea eggs, flea larvae, ticks, mosquitoes and chewing lice
 - Kills, fleas, flea eggs, flea larvae, ticks, mosquitoes and lice
 - Apply monthly for control and prevention of fleas and ticks
 - Protects against fleas and ticks for up to one month
 - EFFIPRO® PLUS Topical Solution for Cats will kill fleas, ticks and chewing lice when applied monthly.
- Fleas: EFFIPRO® PLUS Topical Solution for Cats can control fleas, flea eggs and flea larvae for up to (six weeks) Apply monthly if your cat has fleas that may cause Flea Allergy Dermatitis, or if reinfestation is likely.
- Ticks: EFFIPRO® PLUS Topical Solution for Cats can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.
- Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Cats can kill mosquitoes within 24 hours (for up to 14 days), and within 48 hours (for up to 28 days).
- Notes: Wait at least 30 days before re-application of EFFIPRO® PLUS Topical Solution for Cats. Avoid contact with treated area until dry.

[Fleas]

- Kills newly emerged adult fleas prior to egg-laying
- Kills fleas that may transmit bartonellosis
- Kills fleas that may transmit bartonellosis, tularemia and tapeworm
- Kills fleas that may transmit diseases, including bartonellosis, tularemia and tapeworm
- Kills fleas that may transmit diseases, including bartonellosis, tularemia and tapeworm infestations
- Kills fleas that may transmit diseases, including bartonellosis and tularemia
- Kills fleas, flea eggs and flea larvae
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to (3 months) (90 days)
- Kills flea eggs for up to (3 months) (90 days)
- Sterilizes and kills fleas
- Sterilizes fleas for up to (3 months) (90 days)
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to (3 months) (90 days)
- With pyriproxyfen (IGR) to break flea life cycle
- Dual Action(!): fipronil and pyriproxyfen (IGR) effectively breaks the flea life cycle
- Kill fleas that may cause Flea Allergy Dermatitis (FAD) or flea-bite anemia
- Effective monthly control of adult fleas
- Kills fleas
- Easy to apply, control of (for) fleas that lasts for up to 1 month (4 weeks)
- Protects (your cat and kitten 8 weeks of age or older) from fleas for up to one month (4 weeks)
- Protects from fleas for up to one month (4 weeks)
- Kills adult fleas for up to one month (4 weeks)
- Apply monthly (all year) for control and prevention of fleas
- Regular (monthly) use breaks the flea life cycle
- EFFIPRO® PLUS Topical Solution for Cats (rapidly) kills fleas that may cause Flea Allergy Dermatitis (FAD)
- EFFIPRO® PLUS Topical Solution for Cats kills fleas on your cat
- Kills adult fleas which may cause Flea Allergy Dermatitis (FAD)
- Kills fleas which/that may cause flea-bite anemia
- Fleas do not have to bite to die
- Protects your cat from flea infestation that may cause flea-bite anemia
- The successive feeding activity of fleas on cats may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis (FAD)
- Protects cats and kittens over 8 weeks of age from fleas for up to one month (4 weeks)
- Prevents flea (re-)infestation for up to one month (4 weeks)
- Prevents flea eggs from hatching or developing into larvae or adult stages (for up to 90 days (3 months))

[Ticks]

- Kills all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (including those which [tha] may transmit [carry] Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis, anaplasmosis and cytauxzoonosis)
- Kills ticks, including those that may transmit Lyme disease
- Kills ticks including Deer ticks (which may transmit Lyme disease), American dog ticks (which may transmit Rocky Mountain Spotted Fever), Brown dog ticks (which may transmit ehrlichiosis), and Lone Star ticks (which may transmit hepatzoonosis) for up to one month (4 weeks)
- Kills ticks including Deer ticks (which may transmit Lyme disease), American dog ticks (which may transmit Rocky Mountain Spotted Fever) and Brown dog ticks (which may transmit ehrlichiosis) for up to one month (4 weeks)
- Kills Brown dog ticks (*Rhipicephalus* spp), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp), and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks)
- Kills *Amblyomma americanum* (Lone Star ticks) for up to 4 weeks (for up to one month)
- Protects from ticks for up to one month

[Mosquitoes]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days

(All others]

- Chewing lice infestations are rapidly eliminated
- May be used only on kittens from 8 weeks of age
- Begins working upon application
- Once monthly application
- Single application lasts up to 4 weeks (one month)
- Easy and convenient application (applications)
- Easy to apply spot-on (topical) application
- Convenient, easy to apply
- Convenient to use (easy to apply)
- Convenient to use (easy to apply) topical application
- Convenient topical application (for cats)
- Easy, spot-on (topical) application
- Quick drying, non-greasy
- Available from licensed veterinarians
- 1 (3, 6, 36) applicator(s) (tube[s]) of 0.017 fl oz (0.5 mL)
- 1 (3, 6, 36) applicator(s) (tube[s]) 0.017 fl oz (0.5 mL)
- 1 (3, 6, 36) month(ly) dose(s) (application[s])
- 1 applicator (tube) 1 month(ly) dose
- 3 applicators (tubes) 3 (monthly) doses
- 6 applicators (tubes) 6 (monthly) doses
- 36 applicators (tubes) 36 (monthly) doses
- 1 applicator containing 0.017 fl oz (0.5 mL)
- 3 (6,36) applicators each containing 0.017 fl oz (0.5 mL)
- Remains effective after exposure to sunlight
- Remains effective after bathing
- Remains effective even after bathing, water immersion or exposure to rain or sunlight
- Remains effective even after bathing
- Remains effective after exposure to rain and sunlight
- Still works after bathing, or exposure to sunlight
- EFFIPRO® PLUS Topical Solution for Cats is effective after bathing, shampooing, water immersion, or sunlight exposure.
- Still works after exposure to sunlight
- Waterproof (remains effective after bathing and swimming)



48695000

December 16, 2011

Richard Gebken, PM 10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: EFFIPRO™ PLUS Topical Solution for Cats (EPA File Symbol 2382-TBA);
New Product Application.

Dear Mr. Gebken,

Virbac Animal Health is hereby submitting an application to register the spot-on pesticide product EFFIPRO™ PLUS Topical Solution for Cats.

This product contains fipronil and is similar to the registered product EFFIPRO Topical Solution for Cats (EPA Reg. No 2382-186), except that it also contains the IGR pyriproxifen.

As indicated on Form 8570-34, Virbac is using the selective method to address applicable data requirements for this application pursuant to 40 CFR 152.90. Pursuant to 40 CFR 152.93, Offer to Pay letters are being sent to the submitters of data cited in Virbac's application that were originally submitted within the past 15 years.

Below is a list of the components included with this application:

1. Cover Letter;
2. Transmittal Document;
3. Application for Pesticide Form 8570-1;
4. Confidential Statement of Formula;
5. Formulator's Exemption Form;
6. Data Matrix Form 8570-4 (EUP and TGAI) ;
7. Certification of Data Citation Form 8570-34;
8. Proposed Label - Use Directions 5 copies;
9. 3 copies of bound PR 86-5 compliant study reports supporting registration;
10. Waiver Request for Acute Inhalation Study (attached to Cover Letter);
11. Letter of Self-certification of Child-Resistant Packaging; and
12. Copy of PRIA Check for category R-310 (\$4807).

Child-Resistant Packaging

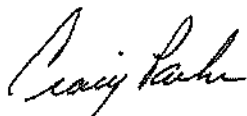
EFFIPRO™ PLUS Topical Solution for Cats employs the same single dose unit applicators that are used in the packaging of the registered product EFFIPRO Topical Solution for Cats. These single dose applicators in packages of 1,3,6, and 36 have been previously tested and CRP certification accepted by EPA. All test data have been cited in the Data Matrix and a Self-Certification letter has been included with this application according to EPA requirements.

PRIA Considerations

After reviewing the Agency's PRIA category interpretations, we believe that the R-310 PRIA category and a 6 month review period is appropriate for this product. Consequently, please find a copy of one previously submitted check in the amount of \$4807.00 to cover the PRIA fee.

Should you have any questions about this application package, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,



Craig Parks, MS, DVM
Vice President, Research & Development
Virbac Animal Health, Inc.

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Virbac, Inc. (EPA Company Number 2382)
P.O. Box 162059
Fort Worth, TX 76161

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is an application to register an end use pro namely EFFIPRO[®] PLUS Topical Solution for Cats. Effipro[®] EFFIPRO[®] PLUS Topical Solution for Cats contains the active ingredients Fipronil and Pyriproxyfen.

SUBMITTAL DATE:

December 16, 2011

Volume	Study Title	MRID No.
1	Administrative Materials Effipro [®] Plus Topical Solution for Cats	
	<i>Group A Product Chemistry</i>	
2	OPPTS 830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1750 Product Specific Chemistry for EFFIPRO [®] PLUS Topical Solution for Cats	48695001
3	OPPTS 830.1700 Preliminary Analysis - Quantification of the Active Ingredients Fipronil and Pyriproxyfen in Five Batches by Validated Methods	48695002
4	OPPTS 830.1800 Enforcement Analytical Method – Quantification of the Active Ingredients Fipronil and Pyriproxyfen	48695003
	<i>Group B Product Chemistry</i>	
5	OPPTS 830.6302, 830.6303, 830.6304 Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)"	48695004
6	OPPTS 830.6314 Determination of Oxidation / Reduction (Chemical Incompatibility)	48695005
7	OPPTS 830.6315 Determination of the Physico-Chemical Property "Flash Point"	48695006

Volume	Study Title	MRID No.
8	OPPTS 830.7000 Determination of the Physico-Chemical Property - pH	48695007
9	OPPTS 830.7100 Determination of Physico-Chemical Property "Viscosity"	48695008
10	OPPTS 830.7300 Determination of the Physico-Chemical Property "Relative Density"	48695009
	<i>Acute Toxicity</i>	
11	OPPTS 870.1100 Acute Oral Toxicity Study in Rats – Up-and-Down Procedure	48695010
12	OPPTS 870.1200 Acute Dermal Toxicity Study in Rats	48695011
13	OPPTS 870.2400 Acute Eye Irritation Study in Rabbits	48695012
14	OPPTS 870.2500 Acute Dermal Irritation Study in Rabbits	48695013
15	OPPTS 870.2600 Dermal sensitization - Contact Hypersensitivity in Albino Guinea Pigs, Buehler Test	48695014
	<i>Product Performance</i>	
16	OPPTS 810.3300 Summary of Efficacy Data	48695015
17	OPPTS 810.3300 Pathogen Transmission Related to Flea and Tick Infestations in Cats and Dogs	48695016
18	OPPTS 810.3300 Study of Efficacy and Safety of 636.29 in Control of Flea Infestation in the Cat	48695017
	<i>Product Safety</i>	
19	OPPTS 870.7200 Summary of Companion Animal Safety Data	48695018
20	OPPTS 870.7200 Tolerance study by Cutaneous Application (spot-on) in Young Cats.	48695019


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: August 23, 2011			EPA Reg No./File Symbol 87825-R		Page 1 of 6
Applicant's/Registrant's Name & Address Virbac SA 1 ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Test Guidelines					
830.1550	Product Identity and Composition	48095240, 48449201	Virbac	OWN	
830.1600	Description of Materials Used	48095240	Virbac	OWN	
830.1620	Description of Production Process	48095239	Virbac	OWN	
830.1650	Description of Formulation Process	48095239	Virbac	OWN	
830.1670	Description of Formation of Impurities	48095240, 48449201	Virbac	OWN	
830.1700	Preliminary Analysis	48095241	Virbac	OWN	
830.1750	Certified Limits	48095240, 48449201	Virbac	OWN	
830.1800	Analytical Method	48095242	Virbac	OWN	
830.1900	Submittal of samples		Virbac	N/A	
830.6302	Color	48095240, 48095243	Virbac	OWN	
830.6303	Physical State	48095240, 48095243	Virbac	OWN	
830.6304	Odor	48095243	Virbac	OWN	
830.6313	Accelerated Storage Stability-Metal Ions	48095243	Virbac	OWN	
830.6314	Oxidation/reduction	48095239	Virbac	OWN	
830.6315	Flammability	48095239	Virbac	OWN	
830.6316	Explodability	48095239	Virbac	NR	
830.6317	1 Yr. Storage Stability		Virbac	OWN	See note page 2
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

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Date August 23, 2011			EPA Reg No./File Symbol 87825-R		Page 2 of 6
Applicant's/Registrant's Name & Address Virbac SA 1 rue avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6318	Viscosity		Virbac	N/A	
830.6319	Miscibility		Virbac	N/A	Solid
830.6320	Corrosion characteristics		Virbac	OWN	See note page 2
830.6321	Dielectric breakdown voltage		Virbac	N/A	Waived
830.7000	pH	48095247	Virbac	OWN	
830.7200	Melting Point	48095249	Virbac	OWN	
830.7300	Density bulk density or specific gravity	48095250	Virbac	OWN	
830.7320	Particle Size		Virbac	N/A	
830.7050	UV/Visible Spectrum	48095248	Virbac	OWN	
830.7370	Dissociation constant	48095251	Virbac	OWN	
830.7520;830.7550; 830.7560 830.7570	Octanol/water partition coefficient	48095244	Virbac	OWN	
830.7840;830.7860	Solubility	48095245	Virbac	OWN	
830.7950	Vapor pressure	48095246	Virbac	OWN	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

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Note: 830.6317 and 830.6320: Per Agency policy, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Virbac has initiated these studies and will submit the final reports if required when the studies are completed.

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DATA MATRIX

Date: August 23, 2011			EPA Reg No./File Symbol 87825-R		Page 3 of 6
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 158.340 Toxicology Data Requirements					
870.1100	Acute oral toxicity	42918628; 43235401 43279706	BASF	OLD	
870.1200	Acute dermal toxicity	42918629	BASF	OLD	
870.1200	Acute dermal toxicity	43235402	BASF	OLD	
870.1300	Acute inhalation toxicity	42918631	BASF	OLD	
870.2400	Primary eye irritation	42918632	BASF	OLD	
870.2500	Primary dermal irritation	42918630	BASF	OLD	
870.2600	Dermal sensitization	42918634	BASF	OLD	
870.6100	Acute delayed neurotoxicity	42918635	BASF	OLD	
870.6100	Acute delayed neurotoxicity	43559501	BASF	OLD	
870.3100	90-day oral toxicity - rodent	42918643	BASF	OLD	
870.3150	90-day oral toxicity - nonrodent	42918642	BASF	OLD	
870.3200	21-day dermal toxicity	42918644	BASF	OLD	
870.3250	90-day dermal toxicity	DATA GAP	BASF	GAP	*See below
870.6100	90-day neurotoxicity - mammal	43291703	BASF	OLD	
81-8	Neurotoxicity to Rats by Acute Oral Administration	44431801	BASF	PAY	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

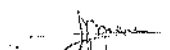
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Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 158.340 Toxicology Data Requirements (Continued)					
84-2	Structural chromosomal aberration	42918680	BASF	OLD	
84-2	Structural chromosomal aberration	42918653	BASF	OLD	
84-2	Other genotoxic effects	42918651;42918653 43501703	BASF	OLD	
85-1/870.7485	General metabolism	42918655	BASF	OLD	
85-1/870.7485	General metabolism	43253701	BASF	PAY	
85-1/870.7485	General metabolism	43737308	BASF	OLD	
85-1/870.7485	General metabolism	42918654	BASF	OLD	
85-1/870.7485	General metabolism	42977904	BASF	OLD	
85-1/870.7485	General metabolism	43253701	BASF	OLD	
85-2/870.7600	Dermal penetration	43737308	BASF	PAY	
85-7/870.7600	Immunotoxicity	DATA GAP		GAP	*See below
40 CFR 158.490 Wildlife and Aquatic Organisms Data Requirements					
71-1/850.2100	Avian oral LD 50 - mallard or bobwhite	42918617 42918616	BASF	OLD	
72-1/850.1075	Freshwater fish LC 50 - rainbow or bluegill	42918624;42918673; 42918674;42977902 43279703;43291718	BASF	OLD OLD OLD	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011


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DATA MATRIX

Date: August 23, 2011			EPA Reg. No./File Symbol 87825-R		Page 5 of 6
Virbac SA tere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
83-1/870.4100	Chronic feeding - rodent	42918648	BASF	OLD	
83-1/870.4100	Chronic feeding - nonrodent	42918645	BASF	OLD	
83-1/870.4100	Chronic feeding - nonrodent	43402802	BASF	PAY	
83-2/870.4200	Oncogenicity - mouse	42918649	BASF	OLD	
83-2/870.4200	Oncogenicity - mouse	43501702	BASF	PAY	
83-2/870.4200	Oncogenicity - rat	42918648	BASF	OLD	
83-3/870.3700	Teratogenicity - rabbit	42918646	BASF	OLD	
83-3/870.3700	Teratogenicity - rat	42977903	BASF	OLD	
83-3/870.3700	Teratogenicity - rat	44275001	BASF	PAY	
83-6/870.6300	Developmental neurotoxicity	44039002	BASF	PAY	
83-4/870.3800	Reproduction	42918647	BASF	OLD	
84-2/870.5100	Gene mutation	42918652	BASF	OLD	
84-2/870.5100	Gene mutation	42918679	BASF	OLD	
84-2/870.5100	Gene mutation	43291716	BASF	OLD	
84-2/870.5100	Gene mutation	43291717	BASF	OLD	
84-2/870.5100	Gene mutation	43291721	BASF	OLD	
84-2/870.5100	Gene mutation	43291722	BASF	OLD	
84-2/870.5100	Gene mutation	43401102	BASF	OLD	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

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Date: August 23, 2011			EPA Reg. No./File Symbol 87825-R	Page 6 of 6
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical	
Ingredient: Fipronil				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status
72-2/850.1010	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	42918625	BASF	OLD
	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	42918669	BASF	OLD
	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	42918671	BASF	OLD
	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	43291719	BASF	OLD
835.2110	Hydrolysis	42977905	BASF	OLD
40 CFR 158.390 Reentry Protection Data Requirements				
133-3	Dermal exposure - Fipronil	44433302	Merial	PAY
133-4	Inhalation exposure - Fipronil	44433302	Merial	PAY
132-1	Dislodgeable residue dissipation - Fipronil	44531203	Merial	PAY
N/A	Dermal and inhalation exposure of commercial pet groomers (Spot) - Fipronil	44433303	Merial	PAY
N/A	Analytical method for exposure studies - Fipronil	44433308	Merial	PAY
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director	
			August 23, 2011	

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* Pursuant to 40 CFR 152.96 (c), Virbac hereby certifies that Virbac has no basis to believe that this requirement is not a data gap and, further, that Virbac has sent by certified mail to all companies on the current EPA Data Submitters List for fipronil a letter requesting that the company identify, within 60 days of receipt, any valid study that would fulfill this data requirement. Once this 60-day period expires, Virbac will update the Agency as to the information, if any, Virbac receives in response to this "data gap" letter.

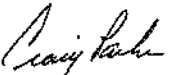


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DATA MATRIX

Dated December 16, 2011			EPA Reg. No./File Symbol 2382-TBA		Page 1 of 1
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Ft. Worth, TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Test Guidelines					
830.1550	Product Identity and Composition	New Submission	Virbac AH, Inc.	OWN	
830.1600	Description of Materials Used	New Submission	Virbac AH, Inc.	OWN	
830.1620	Description of Production Process	New Submission	Virbac AH, Inc.	OWN	
830.1650	Description of Formulation Process	New Submission	Virbac AH, Inc.	OWN	
830.1670	Description of Formation of Impurities	New Submission	Virbac AH, Inc.	OWN	
830.1700	5-Batch Analysis	New Submission	Virbac AH, Inc.	OWN	
830.1750	Certified Limits	New Submission	Virbac AH, Inc.	OWN	
830.1800	Analytical Method	New Submission	Virbac AH, Inc.	OWN	
830.6302	Color	New Submission	Virbac AH, Inc.	OWN	
830.6303	Physical State	New Submission	Virbac AH, Inc.	OWN	
830.6313	Metal Stability		Virbac AH, Inc.	NR	
830.6304	Odor	New Submission	Virbac AH, Inc.	OWN	
830.6314	Oxidation/reduction	New Submission	Virbac AH, Inc.	OWN	
830.6315	Flammability	New Submission	Virbac AH, Inc.	OWN	
830.6316	Explosibility		Virbac AH, Inc.	NR	
830.6317	Storage stability	To Be Conducted	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011

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DATA MATRIX

Date: December 16, 2011			EPA Reg No./File Symbol 2382-TBA		Page 2 of 6
Applicant's/Registrant's Name & Address Virbac AH, Inc. PO Box 162059 Ft. Worth, TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Group B: Series 830 – Physical and Chemical Properties					
830.7100	Viscosity	New Submission	Virbac AH, Inc.	OWN	
830.6319	Miscibility		Virbac AH, Inc.	NR	
830.6320	Corrosion characteristics	To Be Conducted	Virbac AH, Inc.	OWN	
830.6321	Dielectric breakdown voltage		Virbac AH, Inc.	NR	
830.7000	pH	New Submission	Virbac AH, Inc.	OWN	
830.7300	Density, bulk density, or specific gravity	New Submission	Virbac AH, Inc.	OWN	
830.7320	Particle size distribution		Virbac AH, Inc.	NR	
40 CFR 158.340 Toxicology Data Requirements					
870.1100	Acute oral toxicity	New Submission	Virbac AH, Inc.	OWN	
870.1200	Acute dermal toxicity	New Submission	Virbac AH, Inc.	OWN	
870.1300	Acute inhalation toxicity	Waiver	Virbac AH, Inc.	OWN	
870.2400	Primary eye irritation	New Submission	Virbac AH, Inc.	OWN	
870.2500	Primary dermal irritation	New Submission	Virbac AH, Inc.	OWN	
870.2600	Dermal sensitization	New Submission	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011

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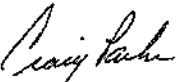
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DATA MATRIX

Date: December 16, 2011			EPA Reg No./File Symbol 2382-TBA		Page 3 of 6
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Ft. Worth, TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.7200	Cat safety	43272401	Merial	OLD	
870.7200	Cat safety	43444904	Merial	OLD	
870.7200	Cat safety	43577711	Merial	OLD	
870.7200	Cat safety	43863801	Merial	OLD	
870.7200	Cat safety	43121112	Merial	OLD	
870.7200	Cat safety	44942009	Merial	PAY	
870.7200	Cat safety	44850103	Virbac	OWN	
870.7200	Cat safety	New submission	Virbac	OWN	
810.3300	Cat efficacy	43121114	Merial	OLD	
810.3300	Cat efficacy	43121115	Merial	OLD	
810.3300	Cat efficacy	43121116	Merial	OLD	
810.3300	Cat efficacy	43121118	Merial	OLD	
810.3300	Cat efficacy	43121119	Merial	OLD	
810.3300	Cat efficacy	43121120	Merial	OLD	
810.3300	Cat efficacy	43121121	Merial	OLD	
810.3300	Cat efficacy	43121122	Merial	OLD	
810.3300	Cat efficacy	43444901	Merial	OLD	
Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011



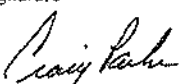
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DATA MATRIX

Date: December 16, 2011			EPA Reg No./File Symbol 2382-TBA		Page 4 of 6
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Ft. Worth, TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Cat efficacy	43577701	Merial	OLD	
810.3300	Cat efficacy	43577712	Merial	OLD	
810.3300	Cat efficacy	43577713	Merial	OLD	
810.3300	Cat efficacy	43951701	Merial	OLD	
810.3300	Cat efficacy	44088901	Merial	PAY	
810.3300	Cat efficacy	44942011	Merial	PAY	
810.3300	Cat efficacy	44942106	Merial	PAY	
810.3300	Cat efficacy	45618501	Merial	PAY	
810.3300	Cat efficacy	45620502	Merial	PAY	
810.3300	Cat efficacy	45620503	Merial	PAY	
810.3300	Cat efficacy	46006002	Wellmark	PUBL	
Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011



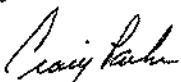
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Date: December 16, 2011			EPA Reg. No./File Symbol 2382-TBA		Page 5 of 6
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Ft. Worth, TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Data					
810.3300	Cat efficacy	45628104	Merial	PAY	
810.3300	Cat efficacy	45628105	Merial	PAY	
810.3300	Cat efficacy	44850104	Virbac	OWN	
810.3300	Cat efficacy	New submission	Virbac	OWN	
810.3300	Cat efficacy	New submission	Virbac	OWN	
810.3300	Cat efficacy	43577712	Merial	OLD	
810.3300	Cat efficacy	43121114	Merial	OLD	
810.3300	Cat efficacy	43121115	Merial	OLD	
810.3300	Cat efficacy	43121117	Merial	OLD	
810.3300	Cat efficacy	43121122	Merial	OLD	
810.3300	Cat efficacy	45620501	Merial	PAY	
810.3300	Cat efficacy	45628101	Merial	PAY	
810.3300	Cat efficacy	45628102	Merial	PAY	
810.3300	Cat efficacy	45628103	Merial	PAY	
810.3300	Cat efficacy	45628201	Merial	PAY	
810.3300	Cat efficacy	45866902	Merial	PAY	
810.3300	Cat efficacy	46019201	Merial	PAY	
810.3300	Cat efficacy	46019202	Merial	PAY	
Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011

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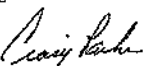


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DATA MATRIX

Dated December 16, 2011			EPA Reg. No./File Symbol 2382-TBA		Page 6 of 6
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Ft. Worth, TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Child Resistant Packaging					
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095215	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 6 applicators tube test for Child-Resistant Effectiveness	48095216	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 36 applicators tube test for Child-Resistant Effectiveness	48095217	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 1 applicator tube test for Senior-Use Effectiveness	48095218	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 6 applicators tube test for Senior-Use Effectiveness	48095219	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 36 applicators tube test for Senior-Use Effectiveness	48095220	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.50 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410018	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.50 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410019	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011

Memorandum

Date: 04/19/12

To: pm 13, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☒ partially accepted submission
☐ rejected submission

resubmission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 19, 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

LANDIS INTERNATIONAL, INC.
MITSUI CHEMICALS AGRO, INC.
PO.BOX : 5126
VALDOSTA, GA 31603-5126

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 13-APR-12. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



LANDIS
INTERNATIONAL

FED EX

Kevin Sweeney
Registration Division (7505P)
US EPA Office of Pesticide Programs
Document Processing Desk
One Potomac Yard, S4900
2777 S. Crystal Drive
Arlington, VA 22202

Date: April 5, 2012

Subject: Etofenprox Technical (EPA Reg. No. 86203-4)
Response to EPA email dated 21 January 2012

On behalf of Mitsui Chemicals Agro, Inc. please find a justification for an analytical enforcement method for livestock for Etofenprox Technical (EPA Reg. No. 86203-4). This justification is being submitted in support of the pending IR-4 amendment (submitted 27 Sep 2011) to the Etofenprox Technical registration to add an "all crop" tolerance. Please find enclosed a CD which contains an e-Dossier of the submission. A data transmittal document is included within the submission to outline the documents being submitted at this time.

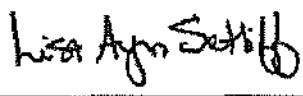
If you have any questions or need additional information, please do not hesitate to contact us at any time (lsetliff@landisintl.com) or via telephone 609-614-7146.

Sincerely,

Lisa Ayn Setliff
Director Regulatory Affairs
Landis International, Inc.
Regulatory Agent for Mitsui Chemicals Agro, Inc.

DATA TRANSMITTAL DOCUMENT**Submitter:**

Mitsui Chemicals Agro, Inc.
 c/o Landis International, Inc.
 PO Box 5126
 Valdosta, GA 31603-5126

Company Contact: 

Typed Name of Signer: Lisa Ayn Setliff

Phone Number: (229) 247-6472

Fax Number: (229) 242-1562

Email Address: lsetliff@landisintl.com

Regulatory Action in Support of Which this Package is Submitted:

EPA Registration Number: 86203-4, Etofenprox Technical
 Response to EPA Email dated January 21, 2012.

Submission Date:

04/05/2012

List of Submitted Documents:

Description	Guideline Number	MRID
Cover Letter	NA	ADMIN
Data Transmittal Document	NA	48790100
EPA Form 8570-1 Application for Registration Etofenprox Technical	NA	ADMIN
Response to EPA Request for Radiovalidation Study (Response to EPA email dated 21 January 2012)	Waiver Request for 860.1340	48790101



LANDIS
INTERNATIONAL

FED EX

Kevin Sweeney
Registration Division (7505P)
US EPA Office of Pesticide Programs
Document Processing Desk
One Potomac Yard, S4900
2777 S. Crystal Drive
Arlington, VA 22202

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Sincerely,

Lisa Ayn Setliff
Director Regulatory Affairs
Landis International, Inc.
Regulatory Agent for Mitsui Chemicals Agro, Inc.

DATA PACKAGE BEAN SHEET

Date: 02-Feb-2012

Page 1 of 2

Decision #: 458840

DP #: (398337)

PRIA

Parent DP #:

Submission #: 908625

E-Sub #:

*** Registration Information ***

Registration: 2382-RII - EFFIPRO PLUS TOPICAL SOLUTION FOR CATS

Company: 2382 - VIRBAC AH, INC.

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Bonaventure Akinlosotu BAKINLOS

Sent Date:

Calculated Due Date: 06-Jul-2012

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: 129032, Pyriproxyfen(11.5%)

129121, Fipronil(9.5%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 02-Feb-2012

Due Back:

DP Ingredient: 129121, Fipronil

129032, Pyriproxyfen

DP Title: Efficacy

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / IB

Last Possible Science Due Date: 06-Jun-2012

Team Name: Efficacy (IB)

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

For your review: R310

MRID 486950 - 05, 16, 17; for a Fipronil + Pyriproxyfen containing Spot-On for cats.

Similar to 2382-186, except it contains the IGR pyriproxyfen. Submits prod chem, tox, efficacy and CAS data; Cites CRP data.

Thanks, B.A

DP#: (398337)

*** Studies Sent for Review ***

Decision#: (458840)

MRID	MRID Status	Citation Reference	Guideline	MRID Status
48695015		Villard, I. (2011) Summary of Efficacy Data for Effipro Plus Topical Solution for Cats (Fipronil 9.5% and Pyriproxyfen 11.5% End Use Product). Project Number: VIRBAC/104/15/2. Unpublished study prepared by Isavet Biosciences. 17p.	810.3300/Treatments to control pests of humans and pets	Pass (18-Jan-2012)
48695016		Parks, C. (2011) Pathogens Transmission Related To Flea and Ticks Infestations in Cats and Dogs: Effipro Plus Topical Solution for Cats (Fipronil 9.5% and Pyriproxyfen 11.5% End Use Product). Project Number: VIRBAC/104/15/3. Unpublished study prepared by Isavet Biosciences. 9p.	810.3300/Treatments to control pests of humans and pets	Pass (18-Jan-2012)
48695017		Ambroggi, G. (1998) Study of Efficacy and Safety of 636.29 in Control of Flea Infestation in the Cat. Project Number: VIRBAC/636/29/0004. Unpublished study prepared by Virbac. 284p.	810.3300/Treatments to control pests of humans and pets	Pass (18-Jan-2012)

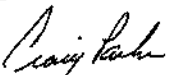


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DATA MATRIX

Dated December 16, 2011			EPA Reg. No./File Symbol 2382-TBA		Page 1 of 1
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Pl. Worth, TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Test Guidelines					
830.1550	Product Identity and Composition	New Submission	Virbac AH, Inc.	OWN	
830.1600	Description of Materials Used	New Submission	Virbac AH, Inc.	OWN	
830.1620	Description of Production Process	New Submission	Virbac AH, Inc.	OWN	
830.1650	Description of Formulation Process	New Submission	Virbac AH, Inc.	OWN	
830.1670	Description of Formation of Impurities	New Submission	Virbac AH, Inc.	OWN	
830.1700	5-Batch Analysis	New Submission	Virbac AH, Inc.	OWN	
830.1750	Certified Limits	New Submission	Virbac AH, Inc.	OWN	
830.1800	Analytical Method	New Submission	Virbac AH, Inc.	OWN	
830.6302	Color	New Submission	Virbac AH, Inc.	OWN	
830.6303	Physical State	New Submission	Virbac AH, Inc.	OWN	
830.6313	Metal Stability		Virbac AH, Inc.	NR	
830.6304	Odor	New Submission	Virbac AH, Inc.	OWN	
830.6314	Oxidation/reduction	New Submission	Virbac AH, Inc.	OWN	
830.6315	Flammability	New Submission	Virbac AH, Inc.	OWN	
830.6316	Explosibility		Virbac AH, Inc.	NR	
830.6317	Storage stability	To Be Conducted	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011

EPA Form 8570-35 (9-97) Electronic and Paper Versions Available. Submit only Paper version.

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Date: December 16, 2011			EPA Reg No./File Symbol 2382-TBA		Page 2 of 6
Applicant's/Registrant's Name & Address Virbac AH, Inc. PO Box 162059 Ft. Worth, TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Group B: Series 830 – Physical and Chemical Properties					
830.7100	Viscosity	New Submission	Virbac AH, Inc.	OWN	
830.6319	Miscibility		Virbac AH, Inc.	NR	
830.6320	Corrosion characteristics	To Be Conducted	Virbac AH, Inc.	OWN	
830.6321	Dielectric breakdown voltage		Virbac AH, Inc.	NR	
830.7060	pH	New Submission	Virbac AH, Inc.	OWN	
830.7300	Density, bulk density, or specific gravity	New Submission	Virbac AH, Inc.	OWN	
830.7320	Particle size distribution		Virbac AH, Inc.	NR	
40 CFR 158.340 Toxicology Data Requirements					
870.1100	Acute oral toxicity	New Submission	Virbac AH, Inc.	OWN	
870.1200	Acute dermal toxicity	New Submission	Virbac AH, Inc.	OWN	
870.1300	Acute inhalation toxicity	Waiver	Virbac AH, Inc.	OWN	
870.2400	Primary eye irritation	New Submission	Virbac AH, Inc.	OWN	
870.2500	Primary dermal irritation	New Submission	Virbac AH, Inc.	OWN	
870.2600	Dermal sensitization	New Submission	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011

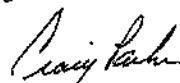


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Date: December 16, 2011			EPA Reg No./File Symbol 2382-T13A		Page 3 of 6
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Ft. Worth, TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MIRID Number	Submitter	Status	Note
870.7200	Cat safety	43272401	Merial	OLD	
870.7200	Cat safety	43444904	Merial	OLD	
870.7200	Cat safety	43577711	Merial	OLD	
870.7200	Cat safety	43863801	Merial	OLD	
870.7200	Cat safety	43121112	Merial	OLD	
870.7200	Cat safety	44942009	Merial	PAY	
870.7200	Cat safety	44850103	Virbac	OWN	
870.7200	Cat safety	New submission	Virbac	OWN	
810.3300	Cat efficacy	43121114	Merial	OLD	
810.3300	Cat efficacy	43121115	Merial	OLD	
810.3300	Cat efficacy	43121116	Merial	OLD	
810.3300	Cat efficacy	43121118	Merial	OLD	
810.3300	Cat efficacy	43121119	Merial	OLD	
810.3300	Cat efficacy	43121120	Merial	OLD	
810.3300	Cat efficacy	43121121	Merial	OLD	
810.3300	Cat efficacy	43121122	Merial	OLD	
810.3300	Cat efficacy	43444901	Merial	OLD	
Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011

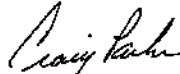


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Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Cat efficacy	43577701	Merial	OLD	
810.3300	Cat efficacy	43577712	Merial	OLD	
810.3300	Cat efficacy	43577713	Merial	OLD	
810.3300	Cat efficacy	43951701	Merial	OLD	
810.3300	Cat efficacy	44088901	Merial	PAY	
810.3300	Cat efficacy	44942011	Merial	PAY	
810.3300	Cat efficacy	44942106	Merial	PAY	
810.3300	Cat efficacy	45618501	Merial	PAY	
810.3300	Cat efficacy	45620502	Merial	PAY	
810.3300	Cat efficacy	45620503	Merial	PAY	
810.3300	Cat efficacy	46006002	Wellmark	PUBL	
Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011

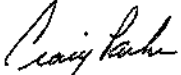
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Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Data					
810.3300	Cat efficacy	45628104	Merial	PAY	
810.3300	Cat efficacy	45628105	Merial	PAY	
810.3300	Cat efficacy	44850104	Virbac	OWN	
810.3300	Cat efficacy	New submission	Virbac	OWN	
810.3300	Cat efficacy	New submission	Virbac	OWN	
810.3300	Cat efficacy	43577712	Merial	OLD	
810.3300	Cat efficacy	43121114	Merial	OLD	
810.3300	Cat efficacy	43121115	Merial	OLD	
810.3300	Cat efficacy	43121117	Merial	OLD	
810.3300	Cat efficacy	43121122	Merial	OLD	
810.3300	Cat efficacy	45620501	Merial	PAY	
810.3300	Cat efficacy	45628101	Merial	PAY	
810.3300	Cat efficacy	45628102	Merial	PAY	
810.3300	Cat efficacy	45628103	Merial	PAY	
810.3300	Cat efficacy	45628201	Merial	PAY	
810.3300	Cat efficacy	45866902	Merial	PAY	
810.3300	Cat efficacy	46019201	Merial	PAY	
810.3300	Cat efficacy	46019202	Merial	PAY	
Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011

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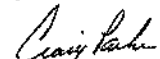
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Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Child Resistant Packaging					
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095215	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 6 applicators tube test for Child-Resistant Effectiveness	48095216	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 36 applicators tube test for Child-Resistant Effectiveness	48095217	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 1 applicator tube test for Senior-Use Effectiveness	48095218	Virbac AH, Inc.	OWN	
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40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 36 applicators tube test for Senior-Use Effectiveness	48095220	Virbac AH, Inc.	OWN	
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40 CFR 157	Evaluation of the 1 ml applicator tube with 0.50 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410019	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011



48695000

December 16, 2011

Richard Gebken, PM 10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: EFFIPRO™ PLUS Topical Solution for Cats (EPA File Symbol 2382-TBA);
New Product Application.

Dear Mr. Gebken,

Virbac Animal Health is hereby submitting an application to register the spot-on pesticide product EFFIPRO™ PLUS Topical Solution for Cats.

This product contains fipronil and is similar to the registered product EFFIPRO Topical Solution for Cats (EPA Reg. No 2382-186), except that it also contains the IGR pyriproxifen.

As indicated on Form 8570-34, Virbac is using the selective method to address applicable data requirements for this application pursuant to 40 CFR 152.90. Pursuant to 40 CFR 152.93, Offer to Pay letters are being sent to the submitters of data cited in Virbac's application that were originally submitted within the past 15 years.

Below is a list of the components included with this application:

1. Cover Letter;
2. Transmittal Document;
3. Application for Pesticide Form 8570-1;
4. Confidential Statement of Formula;
5. Formulator's Exemption Form;
6. Data Matrix Form 8570-4 (EUP and TGAI) ;
7. Certification of Data Citation Form 8570-34;
8. Proposed Label - Use Directions 5 copies;
9. 3 copies of bound PR 86-5 compliant study reports supporting registration;
10. Waiver Request for Acute Inhalation Study (attached to Cover Letter);
11. Letter of Self-certification of Child-Resistant Packaging; and
12. Copy of PRIA Check for category R-310 (\$4807).

Child-Resistant Packaging

EFFIPRO™ PLUS Topical Solution for Cats employs the same single dose unit applicators that are used in the packaging of the registered product EFFIPRO Topical Solution for Cats. These single dose applicators in packages of 1,3,6, and 36 have been previously tested and CRP certification accepted by EPA. All test data have been cited in the Data Matrix and a Self-Certification letter has been included with this application according to EPA requirements.

PRIA Considerations

After reviewing the Agency's PRIA category interpretations, we believe that the R-310 PRIA category and a 6 month review period is appropriate for this product. Consequently, please find a copy of one previously submitted check in the amount of \$4807.00 to cover the PRIA fee.

Should you have any questions about this application package, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,



Craig Parks, MS, DVM
Vice President, Research & Development
Virbac Animal Health, Inc.

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Virbac, Inc. (EPA Company Number 2382)
P.O. Box 162059
Fort Worth, TX 76161

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is an application to register an end use pro namely EFFIPRO® PLUS Topical Solution for Cats. Effipro® EFFIPRO® PLUS Topical Solution for Cats contains the active ingredients Fipronil and Pyriproxyfen.

SUBMITTAL DATE:

December 16, 2011

Volume	Study Title	MRID No.
1	Administrative Materials Effipro® Plus Topical Solution for Cats	
	<i>Group A Product Chemistry</i>	
2	OPPTS 830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1750 Product Specific Chemistry for EFFIPRO® PLUS Topical Solution for Cats	48695001
3	OPPTS 830.1700 Preliminary Analysis - Quantification of the Active Ingredients Fipronil and Pyriproxyfen in Five Batches by Validated Methods	48695002
4	OPPTS 830.1800 Enforcement Analytical Method – Quantification of the Active Ingredients Fipronil and Pyriproxyfen	48695003
	<i>Group B Product Chemistry</i>	
5	OPPTS 830.6302, 830.6303, 830.6304 Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)"	48695004
6	OPPTS 830.6314 Determination of Oxidation / Reduction (Chemical Incompatibility)	48695005
7	OPPTS 830.6315 Determination of the Physico-Chemical Property "Flash Point"	48695006

Volume	Study Title	MRID No.
8	OPPTS 830.7000 Determination of the Physico-Chemical Property - pH	48695007
9	OPPTS 830.7100 Determination of Physico-Chemical Property "Viscosity"	48695008
10	OPPTS 830.7300 Determination of the Physico-Chemical Property "Relative Density"	48695009
	<i>Acute Toxicity</i>	
11	OPPTS 870.1100 Acute Oral Toxicity Study in Rats – Up-and-Down Procedure	48695010
12	OPPTS 870.1200 Acute Dermal Toxicity Study in Rats	48695011
13	OPPTS 870.2400 Acute Eye Irritation Study in Rabbits	48695012
14	OPPTS 870.2500 Acute Dermal Irritation Study in Rabbits	48695013
15	OPPTS 870.2600 Dermal sensitization - Contact Hypersensitivity in Albino Guinea Pigs, Buehler Test	48695014
	<i>Product Performance</i>	
16	OPPTS 810.3300 Summary of Efficacy Data	48695015
17	OPPTS 810.3300 Pathogen Transmission Related to Flea and Tick Infestations in Cats and Dogs	48695016
18	OPPTS 810.3300 Study of Efficacy and Safety of 636.29 in Control of Flea Infestation in the Cat	48695017
	<i>Product Safety</i>	
19	OPPTS 870.7200 Summary of Companion Animal Safety Data	48695018
20	OPPTS 870.7200 Tolerance study by Cutaneous Application (spot-on) in Young Cats.	48695019


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DATA MATRIX

Date: August 23, 2011			EPA Reg. No./File Symbol 87825-R		Page 6 of 6
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Role
72-2/850.1010	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	42918625	BASF	OLD	
	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	42918669	BASF	OLD	
	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	42918671	BASF	OLD	
	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	43291719	BASF	OLD	
835.2110	Hydrolysis	42977905	BASF	OLD	
40 CFR 158.390 Reentry Protection Data Requirements					
133-3	Dermal exposure - Fipronil	44433302	Merial	PAY	
133-4	Inhalation exposure - Fipronil	44433302	Merial	PAY	
132-1	Dislodgeable residue dissipation - Fipronil	44531203	Merial	PAY	
N/A	Dermal and inhalation exposure of commercial pet groomers (Spot) - Fipronil	44433303	Merial	PAY	
N/A	Analytical method for exposure studies - Fipronil	44433308	Merial	PAY	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		August 23, 2011

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* Pursuant to 40 CFR 152.96 (c), Virbac hereby certifies that Virbac has no basis to believe that this requirement is not a data gap and, further, that Virbac has sent by certified mail to all companies on the current EPA Data Submitters List for fipronil a letter requesting that the company identify, within 60 days of receipt, any valid study that would fulfill this data requirement. Once this 60-day period expires, Virbac will update the Agency as to the information, if any, Virbac receives in response to this "data gap" letter.

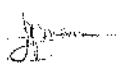


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DATA MATRIX

Date: August 23, 2011			EPA Reg. No./Fife Symbol 87825-R		Page 5 of 6
Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
83-1/870.4100	Chronic feeding – rodent	42918648	BASF	OLD	
83-1/870.4100	Chronic feeding – nonrodent	42918645	BASF	OLD	
83-1/870.4100	Chronic feeding – nonrodent	43402802	BASF	PAY	
83-2/870.4200	Oncogenicity – mouse	42918649	BASF	OLD	
83-2/870.4200	Oncogenicity – mouse	43501702	BASF	PAY	
83-2/870.4200	Oncogenicity – rat	42918648	BASF	OLD	
83-3/870.3700	Teratogenicity – rabbit	42918646	BASF	OLD	
83-3/870.3700	Teratogenicity – rat	42977903	BASF	OLD	
83-3/870.3700	Teratogenicity – rat	44275001	BASF	PAY	
83-6/870.6300	Developmental neurotoxicity	44039002	BASF	PAY	
83-4/870.3800	Reproduction	42918647	BASF	OLD	
84-2/870.5100	Gene mutation	42918652	BASF	OLD	
84-2/870.5100	Gene mutation	42918679	BASF	OLD	
84-2/870.5100	Gene mutation	43291716	BASF	OLD	
84-2/870.5100	Gene mutation	43291717	BASF	OLD	
84-2/870.5100	Gene mutation	43291721	BASF	OLD	
84-2/870.5100	Gene mutation	43291722	BASF	OLD	
84-2/870.5100	Gene mutation	43401102	BASF	OLD	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011



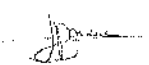
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DATA MATRIX

Date August 23, 2011			EPA Reg No./File Symbol 87825-R		Page 4 of 6
Applicant's/Registrant's Name & Address Virbac SA 1 ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 158.340 Toxicology Data Requirements (Continued)					
84-2	Structural chromosomal aberration	42918680	BASF	OLD	
84-2	Structural chromosomal aberration	42918653	BASF	OLD	
84-2	Other genotoxic effects	42918651;42918653 43501703	BASF	OLD	
85-1/870.7485	General metabolism	42918655	BASF	OLD	
85-1/870.7485	General metabolism	43253701	BASF	PAY	
85-1/870.7485	General metabolism	43737308	BASF	OLD	
85-1/870.7485	General metabolism	42918654	BASF	OLD	
85-1/870.7485	General metabolism	42977904	BASF	OLD	
85-1/870.7485	General metabolism	43253701	BASF	OLD	
85-2/870.7600	Dermal penetration	43737308	BASF	PAY	
85-7/870.7600	Immunotoxicity	DATA GAP		GAP	*See below
40 CFR 158.490 Wildlife and Aquatic Organisms Data Requirements					
71-1/850.2100	Avian oral LD 50 - mallard or bobwhite	42918617 42918616	BASF	OLD	
72-1/850.1075	Freshwater fish LC 50 - rainbow or bluegill	42918624;42918673; 42918674;42977902 43279703;43291718	BASF	OLD OLD OLD	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

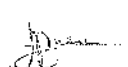


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Applicant's/Registrant's Name & Address Virbac SA tere avenue 2065 M - LID F-06516 Carros, France		Product: Fipronil Technical			
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 158.340 Toxicology Data Requirements					
870.1100	Acute oral toxicity	42918628; 43235401 43279706	BASF	OLD	
870.1200	Acute dermal toxicity	42918629	BASF	OLD	
870.1200	Acute dermal toxicity	43235402	BASF	OLD	
870.1300	Acute inhalation toxicity	42918631	BASF	OLD	
870.2400	Primary eye irritation	42918632	BASF	OLD	
870.2500	Primary dermal irritation	42918630	BASF	OLD	
870.2600	Dermal sensitization	42918634	BASF	OLD	
870.6100	Acute delayed neurotoxicity	42918635	BASF	OLD	
870.6100	Acute delayed neurotoxicity	43559501	BASF	OLD	
870.3100	90-day oral toxicity - rodent	42918643	BASF	OLD	
870.3150	90-day oral toxicity - nonrodent	42918642	BASF	OLD	
870.3200	21-day dermal toxicity	42918644	BASF	OLD	
870.3250	90-day dermal toxicity	DATA GAP	BASF	GAP	*See below
870.6100	90-day neurotoxicity - mammal	43291703	BASF	OLD	
81-8	Neurotoxicity to Rats by Acute Oral Administration	44431801	BASF	PAY	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

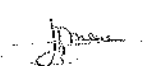


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DATA MATRIX

Date August 23, 2011			EPA Reg No./File Symbol 87825-R		Page 2 of 3
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6318	Viscosity		Virbac	N/A	
830.6319	Miscibility		Virbac	N/A	Solid
830.6320	Corrosion characteristics		Virbac	OWN	See note page 2
830.6321	Dielectric breakdown voltage		Virbac	N/A	Waived
830.7000	pH	48095247	Virbac	OWN	
830.7200	Melting Point	48095249	Virbac	OWN	
830.7300	Density bulk density or specific gravity	48095250	Virbac	OWN	
830.7320	Particle Size		Virbac	N/A	
830.7050	UV/Visible Spectrum	48095248	Virbac	OWN	
830.7370	Dissociation constant	48095251	Virbac	OWN	
830.7520;830.7550; 830.7560 830.7570	Octanol/water partition coefficient	48095244	Virbac	OWN	
830.7840;830.7860	Solubility	48095245	Virbac	OWN	
830.7950	Vapor pressure	48095246	Virbac	OWN	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

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Note: 830.6317 and 830.6320: Per Agency policy, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Virbac has initiated these studies and will submit the final reports if required when the studies are completed.




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Date: August 23, 2011			EPA Reg No./File Symbol 87825-R		Page 1 of 6
Applicant's/Registrant's Name & Address Virbac SA 1 cre avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Test Guidelines					
830.1550	Product Identity and Composition	48095240, 48449201	Virbac.	OWN	
830.1600	Description of Materials Used	48095240	Virbac	OWN	
830.1620	Description of Production Process	48095239	Virbac	OWN	
830.1650	Description of Formulation Process	48095239	Virbac	OWN	
830.1670	Description of Formation of Impurities	48095240, 48449201	Virbac	OWN	
830.1700	Preliminary Analysis	48095241	Virbac	OWN	
830.1750	Certified Limits	48095240, 48449201	Virbac	OWN	
830.1800	Analytical Method	48095242	Virbac	OWN	
830.1900	Submittal of samples		Virbac	N/A	
830.6302	Color	48095240, 48095243	Virbac	OWN	
830.6303	Physical State	48095240, 48095243	Virbac	OWN	
830.6304	Odor	48095243	Virbac	OWN	
830.6313	Accelerated Storage Stability-Metal Ions	48095243	Virbac	OWN	
830.6314	Oxidation/reduction	48095239	Virbac	OWN	
830.6315	Flammability	48095239	Virbac	OWN	
830.6316	Explosibility	48095239	Virbac	NR	
830.6317	1 Yr. Storage Stability		Virbac	OWN	See note page 2
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

{Master Label}

Virbac's Master Label

Date December 13, 2011 Version US-7 EPA Reg. No. 2382-XXX
Fipronil + Pyriproxyfen Topical Solution for Cats

Virbac

EFFIPRO[®] PLUS TOPICAL SOLUTION FOR CATS

FOR USE ONLY ON CATS AND KITTENS 8 WEEKS OLD OR OLDER

ACTIVE INGREDIENTS:

Fipronil9.5%
Pyriproxyfen.....11.5%

OTHER INGREDIENTS: 79.0%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ ENTIRE LABEL BEFORE EACH USE

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Possible temporary irritation may occur at the site where EFFIPRO[®] PLUS Topical Solution for Cats was applied. Contact a veterinarian immediately if signs become persistent or become more severe during the first few days following application. If an unusual reaction is observed following initial application, a veterinarian should be consulted before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged cats.

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents.	

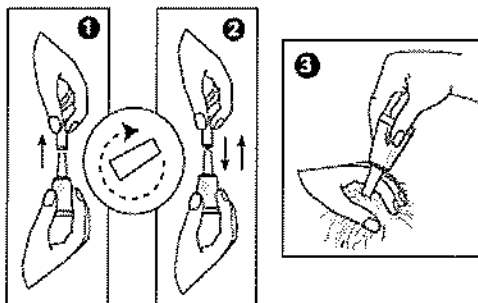
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

For killing fleas, flea eggs, flea larvae, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that (which) may transmit (carry) Lyme disease), mosquitoes, and chewing lice; apply to CATS or KITTENS (8 weeks old or older) as follows:

APPLICATION DIRECTIONS

1. Remove one applicator from packaging.
Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator tip.
Push cap down to break seal.
Remove cap prior to treatment application.
3. Part cat's hair between shoulder blades until skin is visible.
Place applicator tip directly against exposed skin.
Deposit entire contents by squeezing the applicator at a single site on cat's skin.
Ensure that EFFIPRO® PLUS Topical Solution for Cats is not applied superficially on cat's hair.



FREQUENCY OF APPLICATION

EFFIPRO® PLUS Topical Solution for Cats will kill fleas, ticks and chewing lice when applied monthly.

Fleas: EFFIPRO® PLUS Topical Solution for Cats can control fleas for up to six weeks. Apply monthly if your cat has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely. EFFIPRO® PLUS Topical Solution for Cats can control flea eggs (and larvae) for up to three months (90 days).

Ticks: EFFIPRO® PLUS Topical Solution for Cats can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.

Chewing Lice: EFFIPRO® PLUS can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Cats can kill mosquitoes within 24 hours (for up to 14 days), and within 48 hours (for up to 28 days).

Notes: Wait at least 30 days before re-application of EFFIPRO® PLUS Topical Solution for Cats. Avoid contact with treated area until dry.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE /CONTAINER DISPOSAL: If empty: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND DISCLAIMER

To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this product not in accordance with directions. Buyer and user assume all risks of use and handling of this material when such use and handling are contrary to label instructions. To the extent consistent with applicable law, any damage arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.

Net Contents: 1, 3, 6 or 36 single-dose applicator(s) per package. Each applicator contains 0.017 fl oz (0.5 mL) of solution.

(Detachable) calendar (monthly application) reminder stickers with (illustration of cat or kitten).

EPA Reg. No. 2382-XXX

EPA Est. No. 2382-XXX

VIRBAC AH, INC.
PO BOX 162059
FORT WORTH, TX 76161
1-800-338-3659

Made In France
EFFIPRO® is a registered trademark of Virbac S.A. in the United States.
Questions or comments?
Call: 1-800-338-3659

{Text for Front Panel, Back Panel and Side Panel}

See package insert(s) for directions for use and frequency of application
Open resealable label for directions for use
Open resealable label for directions for use and storage and disposal
See back panel for additional precautionary statements
See package insert(s) for frequency of application
See enclosed insert(s) for directions for use and storage and disposal
See enclosed insert(s) for directions for use

Use only on cats
For Use on Cats only
Only for cats and kittens 8 weeks old or older
(1, 3, 6 or 36) applicator(s) 0.017 fl oz (0.5 ml)

Photograph of cat or kitten

Lift here to open (LIFT HERE TO OPEN)

{Text for Foil of Blister package}

Virbac
EFFIPRO® PLUS Topical Solution for Cats
Only for use on cats / 0.017 fl oz (0.5 ml)
Contains fipronil (9.5%) and pyriproxyfen (1 t.5%)
KEEP OUT OF REACH OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-XXX

{Text for Applicator Tube}

Virbac
EFFIPRO® PLUS
Topical Solution for Cats
Only for use on cats
0.017 fl oz (0.5 mL)
Contains fipronil (9.5%) and pyriproxyfen (11.5%)
KEEP OUT OF REACH
OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-XXX

MARKETING CLAIMS

[Multiple infestations]

- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea larvae, ticks, mosquitoes and chewing lice (for CATS and KITTENS 8 weeks old or older).
- For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing lice (for CATS and KITTENS 8 weeks old or older).
- EFFIPRO® PLUS Topical Solution for Cats contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice (on cats) (8 weeks old or older).
- EFFIPRO® PLUS Topical Solution for Cats contains the active ingredient pyriproxyfen, which controls reinfestation caused by flea eggs, flea larvae (on cats) (8 weeks old or older).
- For killing fleas, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks, (which/that may carry (transmit) Lyme disease), mosquitoes and chewing lice; apply to CATS or KITTENS (8 weeks old or older) as follows: (followed by application directions).
- Persistent flea and tick efficacy for up to one month (4 weeks) (30 days)
- Prevents flea and tick (re-)infestation for up to one month (4 weeks)
- Effective monthly application for (on) fleas and ticks

- Effective monthly application for cats (and kittens) against fleas and ticks
 - Kills fleas and ticks for up to one month (4 weeks)
 - Kills fleas, ticks, mosquitoes and chewing lice
 - Kills fleas, ticks, mosquitoes and lice
 - Kills, fleas, flea eggs, flea larvae, ticks, mosquitoes and chewing lice
 - Kills, fleas, flea eggs, flea larvae, ticks, mosquitoes and lice
 - Apply monthly for control and prevention of fleas and ticks
 - Protects against fleas and ticks for up to one month
 - EFFIPRO[®] PLUS Topical Solution for Cats will kill fleas, ticks and chewing lice when applied monthly.
- Fleas: EFFIPRO[®] PLUS Topical Solution for Cats can control fleas, flea eggs and flea larvae for up to (six weeks) Apply monthly if your cat has fleas that may cause Flea Allergy Dermatitis, or if reinfestation is likely.
- Ticks: EFFIPRO[®] PLUS Topical Solution for Cats can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.
- Mosquitoes: When applied monthly, EFFIPRO[®] PLUS Topical Solution for Cats can kill mosquitoes within 24 hours (for up to 14 days), and within 48 hours (for up to 28 days).
- Notes: Wait at least 30 days before re-application of EFFIPRO[®] PLUS Topical Solution for Cats. Avoid contact with treated area until dry.

[Fleas]

- Kills newly emerged adult fleas prior to egg-laying
- Kills fleas that may transmit bartonellosis
- Kills fleas that may transmit bartonellosis, tularemia and tapeworm
- Kills fleas that may transmit diseases, including bartonellosis, tularemia and tapeworm
- Kills fleas that may transmit diseases, including bartonellosis, tularemia and tapeworm infestations
- Kills fleas that may transmit diseases, including bartonellosis and tularemia
- Kills fleas, flea eggs and flea larvae
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to (3 months) (90 days)
- Kills flea eggs for up to (3 months) (90 days)
- Sterilizes and kills fleas
- Sterilizes fleas for up to (3 months) (90 days)
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to (3 months) (90 days)
- With pyriproxyfen (IGR) to break flea life cycle
- Dual Action(!): fipronil and pyriproxyfen (IGR) effectively breaks the flea life cycle
- Kill fleas that may cause Flea Allergy Dermatitis (FAD) or flea-bite anemia
- Effective monthly control of adult fleas
- Kills fleas
- Easy to apply, control of (for) fleas that lasts for up to 1 month (4 weeks)
- Protects (your cat and kitten 8 weeks of age or older) from fleas for up to one month (4 weeks)
- Protects from fleas for up to one month (4 weeks)
- Kills adult fleas for up to one month (4 weeks)
- Apply monthly (all year) for control and prevention of fleas
- Regular (monthly) use breaks the flea life cycle
- EFFIPRO[®] PLUS Topical Solution for Cats (rapidly) kills fleas that may cause Flea Allergy Dermatitis (FAD)
- EFFIPRO[®] PLUS Topical Solution for Cats kills fleas on your cat
- Kills adult fleas which may cause Flea Allergy Dermatitis (FAD)
- Kills fleas which/that may cause flea-bite anemia
- Fleas do not have to bite to die
- Protects your cat from flea infestation that may cause flea-bite anemia
- The successive feeding activity of fleas on cats may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis (FAD)
- Protects cats and kittens over 8 weeks of age from fleas for up to one month (4 weeks)
- Prevents flea (re-)infestation for up to one month (4 weeks)
- Prevents flea eggs from hatching or developing into larvae or adult stages (for up to 90 days (3 months))

[Ticks]

- Kills all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (including those which [that] may transmit [carry] Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis, anaplasmosis and cytauxzoonosis)
- Kills ticks, including those that may transmit Lyme disease
- Kills ticks including Deer ticks (which may transmit Lyme disease), American dog ticks (which may transmit Rocky Mountain Spotted Fever), Brown dog ticks (which may transmit ehrlichiosis), and Lone Star ticks (which may transmit hepatozoonosis) for up to one month (4 weeks)
- Kills ticks including Deer ticks (which may transmit Lyme disease), American dog ticks (which may transmit Rocky Mountain Spotted Fever) and Brown dog ticks (which may transmit ehrlichiosis) for up to one month (4 weeks)
- Kills Brown dog ticks (*Rhipicephalus* spp), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp), and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks)
- Kills *Amblyomma americanum* (Lone Star ticks) for up to 4 weeks (for up to one month)
- Protects from ticks for up to one month

[Mosquitoes]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days

[All others)

- Chewing lice infestations are rapidly eliminated
- May be used only on kittens from 8 weeks of age
- Begins working upon application
- Once monthly application
- Single application lasts up to 4 weeks (one month)
- Easy and convenient application (applications)
- Easy to apply spot-on (topical) application
- Convenient, easy to apply
- Convenient to use (easy to apply)
- Convenient to use (easy to apply) topical application
- Convenient topical application (for cats)
- Easy, spot-on (topical) application
- Quick drying, non-greasy
- Available from licensed veterinarians
- 1 (3, 6, 36) applicator(s) (tube[s]) of 0.017 fl oz (0.5 mL)
- 1 (3, 6, 36) applicator(s) (tube[s]) 0.017 fl oz (0.5 mL)
- 1 (3, 6, 36) month(ly) dose(s) (application(s))
- 1 applicator (tube) 1 month(ly) dose
- 3 applicators (tubes) 3 (monthly) doses
- 6 applicators (tubes) 6 (monthly) doses
- 36 applicators (tubes) 36 (monthly) doses
- 1 applicator containing 0.017 fl oz (0.5 mL)
- 3 (6,36) applicators each containing 0.017 fl oz (0.5 mL)
- Remains effective after exposure to sunlight
- Remains effective after bathing
- Remains effective even after bathing, water immersion or exposure to rain or sunlight
- Remains effective even after bathing
- Remains effective after exposure to rain and sunlight
- Still works after bathing, or exposure to sunlight
- EFFIPRO[®] PLUS Topical Solution for Cats is effective after bathing, shampooing, water immersion, or sunlight exposure.
- Still works after exposure to sunlight
- Waterproof (remains effective after bathing and swimming)

{Master Label}
Virbac's Master Label

Date December 13, 2011 Version US-7 EPA Reg. No. 2382-XXX
 Fipronil + Pyriproxyfen Topical Solution for Cats

Virbac
EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS

FOR USE ONLY ON CATS AND KITTENS 8 WEEKS OLD OR OLDER

ACTIVE INGREDIENTS:

Fipronil 9.5%
 Pyriproxyfen 11.5%

OTHER INGREDIENTS: 79.0%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION
 READ ENTIRE LABEL BEFORE EACH USE

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Possible temporary irritation may occur at the site where EFFIPRO® PLUS Topical Solution for Cats was applied. Contact a veterinarian immediately if signs become persistent or become more severe during the first few days following application. If an unusual reaction is observed following initial application, a veterinarian should be consulted before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged cats.

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents.	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

{Master Label}
Virbac's Master Label

Date December 13, 2011 Version US-7 EPA Reg. No. 2382-XXX
 Fipronil + Pyriproxyfen Topical Solution for Cats

Virbac
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CAUTION

READ ENTIRE LABEL BEFORE EACH USE

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Possible temporary irritation may occur at the site where EFFIPRO[®] PLUS Topical Solution for Cats was applied. Contact a veterinarian immediately if signs become persistent or become more severe during the first few days following application. If an unusual reaction is observed following initial application, a veterinarian should be consulted before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged cats.

	FIRST AID
IF SWALLOWED:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents.	

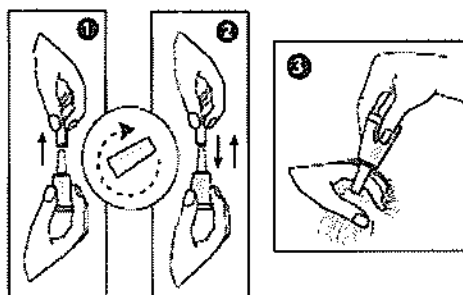
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

For killing fleas, flea eggs, flea larvae, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that [which] may transmit [carry] Lyme disease), mosquitoes, and chewing lice; apply to CATS or KITTENS (8 weeks old or older) as follows:

APPLICATION DIRECTIONS

1. Remove one applicator from packaging.
Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator tip.
Push cap down to break seal.
Remove cap prior to treatment application.
3. Part cat's hair between shoulder blades until skin is visible.
Place applicator tip directly against exposed skin.
Deposit entire contents by squeezing the applicator at a single site on cat's skin.
Ensure that EFFIPRO® PLUS Topical Solution for Cats is not applied superficially on cat's hair.



FREQUENCY OF APPLICATION

EFFIPRO® PLUS Topical Solution for Cats will kill fleas, ticks and chewing lice when applied monthly.

Fleas: EFFIPRO® PLUS Topical Solution for Cats can control fleas for up to six weeks. Apply monthly if your cat has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely. EFFIPRO® PLUS Topical Solution for Cats can control flea eggs (and larvae) for up to three months (90 days).

Ticks: EFFIPRO® PLUS Topical Solution for Cats can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.

Chewing Lice: EFFIPRO® PLUS can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Cats can kill mosquitoes within 24 hours (for up to 14 days), and within 48 hours (for up to 28 days).

Notes: Wait at least 30 days before re-application of EFFIPRO® PLUS Topical Solution for Cats. Avoid contact with treated area until dry.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE (CONTAINER) DISPOSAL: If empty: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND DISCLAIMER

To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this product not in accordance with directions. Buyer and user assume all risks of use and handling of this material when such use and handling are contrary to label instructions. To the extent consistent with applicable law, any damage arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.

Net Contents: 1, 3, 6 or 36 single-dose applicator(s) per package. Each applicator contains 0.017 fl oz (0.5 mL) of solution.

(Detachable) calendar (monthly application) reminder stickers with (illustration of cat or kitten).

EPA Reg. No. 2382-XXX

EPA Est. No. 2382-XXX

VIRBAC AH, INC.
PO BOX 162059
FORT WORTH, TX 76161
1-800-338-3659

Made in France
EFFIPRO® is a registered trademark of Virbac S.A. in the United States.
Questions or comments?
Call: 1-800-338-3659

{Text for Front Panel, Back Panel and Side Panel}

See package insert(s) for directions for use and frequency of application
Open resealable label for directions for use
Open resealable label for directions for use and storage and disposal
See back panel for additional precautionary statements
See package insert(s) for frequency of application
See enclosed insert(s) for directions for use and storage and disposal
See enclosed insert(s) for directions for use

Use only on cats
For Use on Cats only
Only for cats and kittens 8 weeks old or older
(1, 3, 6 or 36) applicator(s) 0.017 fl oz (0.5 ml)

Photograph of cat or kitten

Lift here to open (LIFT HERE TO OPEN)

{Text for Foil of Blister package}

Virbac
EFFIPRO® PLUS Topical Solution for Cats
Only for use on cats / 0.017 fl oz (0.5 ml)
Contains fipronil (9.5%) and pyriproxyfen (1.5%)
KEEP OUT OF REACH OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-XXX

{Text for Applicator Tube}

Virbac
EFFIPRO® PLUS
Topical Solution for Cats
Only for use on cats
0.017 fl oz (0.5 mL)
Contains fipronil (9.5%) and pyriproxyfen (1.5%)
KEEP OUT OF REACH
OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-XXX

MARKETING CLAIMS

[Multiple Infestations]

- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea larvae, ticks, mosquitoes and chewing lice (for CATS and KITTENS 8 weeks old or older).
- For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing lice (for CATS and KITTENS 8 weeks old or older).
- EFFIPRO® PLUS Topical Solution for Cats contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice (on cats) (8 weeks old or older).
- EFFIPRO® PLUS Topical Solution for Cats contains the active ingredient pyriproxyfen, which controls reinfestation caused by flea eggs, flea larvae (on cats) (8 weeks old or older).
- For killing fleas, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks, (which/that may carry (transmit) Lyme disease), mosquitoes and chewing lice; apply to CATS or KITTENS (8 weeks old or older) as follows: (followed by application directions).
- Persistent flea and tick efficacy for up to one month (4 weeks) (30 days)
- Prevents flea and tick (re-)infestation for up to one month (4 weeks)
- Effective monthly application for (on) fleas and ticks

- Effective monthly application for cats (and kittens) against fleas and ticks
- Kills fleas and ticks for up to one month (4 weeks)
- Kills fleas, ticks, mosquitoes and chewing lice
- Kills fleas, ticks, mosquitoes and lice
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes and chewing lice
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes and lice
- Apply monthly for control and prevention of fleas and ticks
- Protects against fleas and ticks for up to one month
- EFFIPRO[®] PLUS Topical Solution for Cats will kill fleas, ticks and chewing lice when applied monthly.
- Fleas: EFFIPRO[®] PLUS Topical Solution for Cats can control fleas, flea eggs and flea larvae for up to (six weeks)
- Apply monthly if your cat has fleas that may cause Flea Allergy Dermatitis, or if reinfestation is likely.
- Ticks: EFFIPRO[®] PLUS Topical Solution for Cats can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.
- Mosquitoes: When applied monthly, EFFIPRO[®] PLUS Topical Solution for Cats can kill mosquitoes within 24 hours (for up to 14 days), and within 48 hours (for up to 28 days).
- Notes: Wait at least 30 days before re-application of EFFIPRO[®] PLUS Topical Solution for Cats. Avoid contact with treated area until dry.

[Fleas]

- Kills newly emerged adult fleas prior to egg-laying
- Kills fleas that may transmit bartonellosis
- Kills fleas that may transmit bartonellosis, tularemia and tapeworm
- Kills fleas that may transmit diseases, including bartonellosis, tularemia and tapeworm
- Kills fleas that may transmit diseases, including bartonellosis, tularemia and tapeworm infestations
- Kills fleas that may transmit diseases, including bartonellosis and tularemia
- Kills fleas, flea eggs and flea larvae
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to (3 months) (90 days)
- Kills flea eggs for up to (3 months) (90 days)
- Sterilizes and kills fleas
- Sterilizes fleas for up to (3 months) (90 days)
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to (3 months) (90 days)
- With pyriproxyfen (IGR) to break flea life cycle
- Dual Action(!): fipronil and pyriproxyfen (IGR) effectively breaks the flea life cycle
- Kill fleas that may cause Flea Allergy Dermatitis (FAD) or flea-bite anemia
- Effective monthly control of adult fleas
- Kills fleas
- Easy to apply, control of (for) fleas that lasts for up to 1 month (4 weeks)
- Protects (your cat and kitten 8 weeks of age or older) from fleas for up to one month (4 weeks)
- Protects from fleas for up to one month (4 weeks)
- Kills adult fleas for up to one month (4 weeks)
- Apply monthly (all year) for control and prevention of fleas
- Regular (monthly) use breaks the flea life cycle
- EFFIPRO[®] PLUS Topical Solution for Cats (rapidly) kills fleas that may cause Flea Allergy Dermatitis (FAD)
- EFFIPRO[®] PLUS Topical Solution for Cats kills fleas on your cat
- Kills adult fleas which may cause Flea Allergy Dermatitis (FAD)
- Kills fleas which/tha may cause flea-bite anemia
- Fleas do not have to bite to die
- Protects your cat from flea infestation that may cause flea-bite anemia
- The successive feeding activity of fleas on cats may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis (FAD)
- Protects cats and kittens over 8 weeks of age from fleas for up to one month (4 weeks)
- Prevents flea (re-)infestation for up to one month (4 weeks)
- Prevents flea eggs from hatching or developing into larvae or adult stages (for up to 90 days (3 months))

[Ticks]

- Kills all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (including those which [tha] may transmit [carry] Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis, anaplasmosis and cytauxzoonosis)
- Kills ticks, including those that may transmit Lyme disease
- Kills ticks including Deer ticks (which may transmit Lyme disease), American dog ticks (which may transmit Rocky Mountain Spotted Fever), Brown dog ticks (which may transmit ehrlichiosis), and Lone Star ticks (which may transmit hepatozoonosis) for up to one month (4 weeks)
- Kills ticks including Deer ticks (which may transmit Lyme disease), American dog ticks (which may transmit Rocky Mountain Spotted Fever) and Brown dog ticks (which may transmit ehrlichiosis) for up to one month (4 weeks)
- Kills Brown dog ticks (*Rhipicephalus* spp), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp), and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks)
- Kills *Amblyomma americanum* (Lone Star ticks) for up to 4 weeks (for up to one month)
- Protects from ticks for up to one month

[Mosquitoes]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days

[All others]

- Chewing lice infestations are rapidly eliminated
- May be used only on kittens from 8 weeks of age
- Begins working upon application
- Once monthly application
- Single application lasts up to 4 weeks (one month)
- Easy and convenient application (applications)
- Easy to apply spot-on (topical) application
- Convenient, easy to apply
- Convenient to use (easy to apply)
- Convenient to use (easy to apply) topical application
- Convenient topical application (for cats)
- Easy, spot-on (topical) application
- Quick drying, non-greasy
- Available from licensed veterinarians
- 1 (3, 6, 36) applicator(s) (tube[s]) of 0.017 fl oz (0.5 mL)
- 1 (3, 6, 36) applicator(s) (tube[s]) 0.017 fl oz (0.5 mL)
- 1 (3, 6, 36) month(ly) dose(s) (application(s))
- 1 applicator (tube) 1 month(ly) dose
- 3 applicators (tubes) 3 (monthly) doses
- 6 applicators (tubes) 6 (monthly) doses
- 36 applicators (tubes) 36 (monthly) doses
- 1 applicator containing 0.017 fl oz (0.5 mL)
- 3 (6,36) applicators each containing 0.017 fl oz (0.5 mL)
- Remains effective after exposure to sunlight
- Remains effective after bathing
- Remains effective even after bathing, water immersion or exposure to rain or sunlight
- Remains effective even after bathing
- Remains effective after exposure to rain and sunlight
- Still works after bathing, or exposure to sunlight
- EFFIPRO® PLUS Topical Solution for Cats is effective after bathing, shampooing, water immersion, or sunlight exposure.
- Still works after exposure to sunlight
- Waterproof (remains effective after bathing and swimming)

{Master Label} Virbac's Master Label

Date December 13, 2011 Version US-7 EPA Reg. No. 2382-XXX
Fipronil + Pyriproxyfen Topical Solution for Cats

Virbac **EFFIPRO[®] PLUS TOPICAL SOLUTION FOR CATS**

FOR USE ONLY ON CATS AND KITTENS 8 WEEKS OLD OR OLDER

ACTIVE INGREDIENTS:

Fipronil9.5%
Pyriproxyfen.....11.5%

OTHER INGREDIENTS:79.0%

TOTAL:100.0%

**KEEP OUT OF REACH OF CHILDREN
CAUTION
READ ENTIRE LABEL BEFORE EACH USE**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Possible temporary irritation may occur at the site where EFFIPRO[®] PLUS Topical Solution for Cats was applied. Contact a veterinarian immediately if signs become persistent or become more severe during the first few days following application. If an unusual reaction is observed following initial application, a veterinarian should be consulted before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged cats.

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
<p>Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents.</p>	

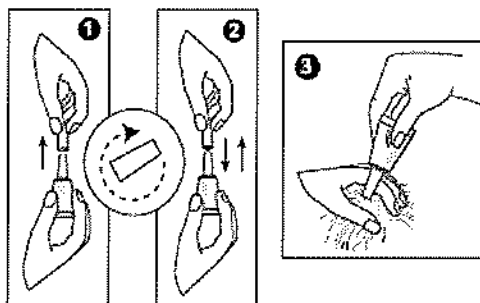
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

For killing fleas, flea eggs, flea larvae, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that [which] may transmit [carry] Lyme disease), mosquitoes, and chewing lice; apply to CATS or KITTENS (8 weeks old or older) as follows:

APPLICATION DIRECTIONS

1. Remove one applicator from packaging.
Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator tip.
Push cap down to break seal.
Remove cap prior to treatment application.
3. Part cat's hair between shoulder blades until skin is visible.
Place applicator tip directly against exposed skin.
Deposit entire contents by squeezing the applicator at a single site on cat's skin.
Ensure that EFFIPRO® PLUS Topical Solution for Cats is not applied superficially on cat's hair.



FREQUENCY OF APPLICATION

EFFIPRO® PLUS Topical Solution for Cats will kill fleas, ticks and chewing lice when applied monthly.

Fleas: EFFIPRO® PLUS Topical Solution for Cats can control fleas for up to six weeks. Apply monthly if your cat has fleas that may cause Flea Allergy Dermatitis (FAD), or if reinfestation is likely. EFFIPRO® PLUS Topical Solution for Cats can control flea eggs (and larvae) for up to three months (90 days).

Ticks: EFFIPRO® PLUS Topical Solution for Cats can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.

Chewing Lice: EFFIPRO® PLUS can kill chewing lice for a month or longer. Apply monthly where chewing lice control is consistently needed.

Mosquitoes: When applied monthly, EFFIPRO® PLUS Topical Solution for Cats can kill mosquitoes within 24 hours (for up to 14 days), and within 48 hours (for up to 28 days).

Notes: Wait at least 30 days before re-application of EFFIPRO® PLUS Topical Solution for Cats. Avoid contact with treated area until dry.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE /CONTAINER DISPOSAL: If empty: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND DISCLAIMER

To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this product not in accordance with directions. Buyer and user assume all risks of use and handling of this material when such use and handling are contrary to label instructions. To the extent consistent with applicable law, any damage arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.

Net Contents: 1, 3, 6 or 36 single-dose applicator(s) per package. Each applicator contains 0.017 fl oz (0.5 mL) of solution.

(Detachable) calendar (monthly application) reminder stickers with (illustration of cat or kitten).

EPA Reg. No. 2382-XXX

EPA Est. No. 2382-XXX

VIRBAC AH, INC.
PO BOX 162059
FORT WORTH, TX 76161
1-800-338-3659

Made in France
EFFIPRO® is a registered trademark of Virbac S.A. in the United States.
Questions or comments?
Call: 1-800-338-3659

{Text for Front Panel, Back Panel and Side Panel}

See package insert(s) for directions for use and frequency of application
Open resealable label for directions for use
Open resealable label for directions for use and storage and disposal
See back panel for additional precautionary statements
See package insert(s) for frequency of application
See enclosed insert(s) for directions for use and storage and disposal
See enclosed insert(s) for directions for use

Use only on cats
For Use on Cats only
Only for cats and kittens 8 weeks old or older
(1, 3, 6 or 36) applicator(s) 0.017 fl oz (0.5 ml)

Photograph of cat or kitten

Lift here to open (LIFT HERE TO OPEN)

{Text for Foil of Blister package}

Virbac
EFFIPRO® PLUS Topical Solution for Cats
Only for use on cats / 0.017 fl oz (0.5 ml)
Contains fipronil (9.5%) and pyriproxyfen (11.5%)
KEEP OUT OF REACH OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-XXX

{Text for Applicator Tube}

Virbac
EFFIPRO® PLUS
Topical Solution for Cats
Only for use on cats
0.017 fl oz (0.5 mL)
Contains fipronil (9.5%) and pyriproxyfen (11.5%)
KEEP OUT OF REACH
OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-XXX

MARKETING CLAIMS

[Multiple infestations]

- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea larvae, ticks, mosquitoes and chewing lice (for CATS and KITTENS 8 weeks old or older).
- For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing lice (for CATS and KITTENS 8 weeks old or older).
- EFFIPRO® PLUS Topical Solution for Cats contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice (on cats) (8 weeks old or older).
- EFFIPRO® PLUS Topical Solution for Cats contains the active ingredient pyriproxyfen, which controls reinfestation caused by flea eggs, flea larvae (on cats) (8 weeks old or older).
- For killing fleas, all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks, (which/that may carry (transmit) Lyme disease), mosquitoes and chewing lice; apply to CATS or KITTENS (8 weeks old or older) as follows: (followed by application directions).
- Persistent flea and tick efficacy for up to one month (4 weeks) (30 days)
- Prevents flea and tick (re-)infestation for up to one month (4 weeks)
- Effective monthly application for (on) fleas and ticks

- Effective monthly application for cats (and kittens) against fleas and ticks
 - Kills fleas and ticks for up to one month (4 weeks)
 - Kills fleas, ticks, mosquitoes and chewing lice
 - Kills fleas, ticks, mosquitoes and lice
 - Kills, fleas, flea eggs, flea larvae, ticks, mosquitoes and chewing lice
 - Kills, fleas, flea eggs, flea larvae, ticks, mosquitoes and lice
 - Apply monthly for control and prevention of fleas and ticks
 - Protects against fleas and ticks for up to one month
 - EFFIPRO® PLUS Topical Solution for Cats will kill fleas, ticks and chewing lice when applied monthly.
- Fleas:** EFFIPRO® PLUS Topical Solution for Cats can control fleas, flea eggs and flea larvae for up to (six weeks) Apply monthly if your cat has fleas that may cause Flea Allergy Dermatitis, or if reinfestation is likely.
- Ticks:** EFFIPRO® PLUS Topical Solution for Cats can kill ticks for a month or longer. Apply monthly where tick control is consistently needed.
- Mosquitoes:** When applied monthly, EFFIPRO® PLUS Topical Solution for Cats can kill mosquitoes within 24 hours (for up to 14 days), and within 48 hours (for up to 28 days).
- Notes:** Wait at least 30 days before re-application of EFFIPRO® PLUS Topical Solution for Cats. Avoid contact with treated area until dry.

[Fleas]

- Kills newly emerged adult fleas prior to egg-laying
- Kills fleas that may transmit bartonellosis
- Kills fleas that may transmit bartonellosis, tularemia and tapeworm
- Kills fleas that may transmit diseases, including bartonellosis, tularemia and tapeworm
- Kills fleas that may transmit diseases, including bartonellosis, tularemia and tapeworm infestations
- Kills fleas that may transmit diseases, including bartonellosis and tularemia
- Kills fleas, flea eggs and flea larvae
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to (3 months) (90 days)
- Kills flea eggs for up to (3 months) (90 days)
- Sterilizes and kills fleas
- Sterilizes fleas for up to (3 months) (90 days)
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to (3 months) (90 days)
- With pyriproxyfen (IGR) to break flea life cycle
- Dual Action(!): fipronil and pyriproxyfen (IGR) effectively breaks the flea life cycle
- Kill fleas that may cause Flea Allergy Dermatitis (FAD) or flea-bite anemia
- Effective monthly control of adult fleas
- Kills fleas
- Easy to apply, control of (for) fleas that lasts for up to 1 month (4 weeks)
- Protects (your cat and kitten 8 weeks of age or older) from fleas for up to one month (4 weeks)
- Protects from fleas for up to one month (4 weeks)
- Kills adult fleas for up to one month (4 weeks)
- Apply monthly (all year) for control and prevention of fleas
- Regular (monthly) use breaks the flea life cycle
- EFFIPRO® PLUS Topical Solution for Cats (rapidly) kills fleas that may cause Flea Allergy Dermatitis (FAD)
- EFFIPRO® PLUS Topical Solution for Cats kills fleas on your cat
- Kills adult fleas which may cause Flea Allergy Dermatitis (FAD)
- Kills fleas which/that may cause flea-bite anemia
- Fleas do not have to bite to die
- Protects your cat from flea infestation that may cause flea-bite anemia
- The successive feeding activity of fleas on cats may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis (FAD)
- Protects cats and kittens over 8 weeks of age from fleas for up to one month (4 weeks)
- Prevents flea (re-)infestation for up to one month (4 weeks)
- Prevents flea eggs from hatching or developing into larvae or adult stages (for up to 90 days (3 months))

[Ticks]

- Kills all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (including those which (that) may transmit [carry] Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis, anaplasmosis and cytauxzoonosis)
- Kills ticks, including those that may transmit Lyme disease
- Kills ticks including Deer ticks (which may transmit Lyme disease), American dog ticks (which may transmit Rocky Mountain Spotted Fever), Brown dog ticks (which may transmit ehrlichiosis), and Lone Star ticks (which may transmit hepatzoonosis) for up to one month (4 weeks)
- Kills ticks including Deer ticks (which may transmit Lyme disease), American dog ticks (which may transmit Rocky Mountain Spotted Fever) and Brown dog ticks (which may transmit ehrlichiosis) for up to one month (4 weeks)
- Kills Brown dog ticks (*Rhipicephalus* spp), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp), and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks)
- Kills *Amblyomma americanum* (Lone Star ticks) for up to 4 weeks (for up to one month)
- Protects from ticks for up to one month

[Mosquitoes]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days

[All others]

- Chewing lice infestations are rapidly eliminated
- May be used only on kittens from 8 weeks of age
- Begins working upon application
- Once monthly application
- Single application lasts up to 4 weeks (one month)
- Easy and convenient application (applications)
- Easy to apply spot-on (topical) application
- Convenient, easy to apply
- Convenient to use (easy to apply)
- Convenient to use (easy to apply) topical application
- Convenient topical application (for cats)
- Easy, spot-on (topical) application
- Quick drying, non-greasy
- Available from licensed veterinarians
- 1 (3, 6, 36) applicator(s) (tube(s)) of 0.017 fl oz (0.5 mL)
- 1 (3, 6, 36) applicator(s) (tube(s)) 0.017 fl oz (0.5 mL)
- 1 (3, 6, 36) month{ly} dose(s) (application)s{}
- 1 applicator (tube) 1 month{ly} dose
- 3 applicators (tubes) 3 (monthly) doses
- 6 applicators (tubes) 6 (monthly) doses
- 36 applicators (tubes) 36 (monthly) doses
- 1 applicator containing 0.017 fl oz (0.5 mL)
- 3 (6,36) applicators each containing 0.017 fl oz (0.5 mL)
- Remains effective after exposure to sunlight
- Remains effective after bathing
- Remains effective even after bathing, water immersion or exposure to rain or sunlight
- Remains effective even after bathing
- Remains effective after exposure to rain and sunlight
- Still works after bathing, or exposure to sunlight
- EFFIPRO[®] PLUS Topical Solution for Cats is effective after bathing, shampooing, water immersion, or sunlight exposure.
- Still works after exposure to sunlight
- Waterproof (remains effective after bathing and swimming)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 29, 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

VIRBAC AH, INC.
VIRBAC AH, INC.
13001 ST. CHARLES ROCK ROAD
BRIDGETON, MO 63044

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 16-DEC-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 19, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-458840
EPA File Symbol or Registration Number: 2382-RII
Product Name: EFFIPRO PLUS TOPICAL SOLUTION FOR CATS
EPA Receipt Date: 16-Dec-2011
EPA Company Number: 2382
Company Name: VIRBAC AH, INC.

CRAIG PARKS
VIRBAC AH, INC.
P.O. BOX 162059
FORT WORTH, TX 76161

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "MSK".

Front End Processing Staff
Information Technology & Resources Management Division



48695000

December 16, 2011

Richard Gebken, PM 10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: EFFIPRO™ PLUS Topical Solution for Cats (EPA File Symbol 2382-TBA);
New Product Application.

Dear Mr. Gebken,

Virbac Animal Health is hereby submitting an application to register the spot-on pesticide product EFFIPRO™ PLUS Topical Solution for Cats.

This product contains fipronil and is similar to the registered product EFFIPRO Topical Solution for Cats (EPA Reg. No 2382-186), except that it also contains the IGR pyriproxifen.

As indicated on Form 8570-34, Virbac is using the selective method to address applicable data requirements for this application pursuant to 40 CFR 152.90. Pursuant to 40 CFR 152.93, Offer to Pay letters are being sent to the submitters of data cited in Virbac's application that were originally submitted within the past 15 years.

Below is a list of the components included with this application:

1. Cover Letter;
2. Transmittal Document;
3. Application for Pesticide Form 8570-1;
4. Confidential Statement of Formula;
5. Formulator's Exemption Form;
6. Data Matrix Form 8570-4 (EUP and TGAI) ;
7. Certification of Data Citation Form 8570-34;
8. Proposed Label - Use Directions 5 copies;
9. 3 copies of bound PR 86-5 compliant study reports supporting registration;
10. Waiver Request for Acute Inhalation Study (attached to Cover Letter);
11. Letter of Self-certification of Child-Resistant Packaging; and
12. Copy of PRIA Check for category R-310 (\$4807).

Child-Resistant Packaging

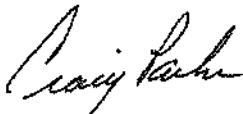
EFFIPRO™ PLUS Topical Solution for Cats employs the same single dose unit applicators that are used in the packaging of the registered product EFFIPRO Topical Solution for Cats. These single dose applicators in packages of 1,3,6, and 36 have been previously tested and CRP certification accepted by EPA. All test data have been cited in the Data Matrix and a Self-Certification letter has been included with this application according to EPA requirements.

PRIA Considerations

After reviewing the Agency's PRIA category interpretations, we believe that the R-310 PRIA category and a 6 month review period is appropriate for this product. Consequently, please find a copy of one previously submitted check in the amount of \$4807.00 to cover the PRIA fee.

Should you have any questions about this application package, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,



Craig Parks, MS, DVM
Vice President, Research & Development
Virbac Animal Health, Inc.

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Virbac, Inc. (EPA Company Number 2382)
P.O. Box 162059
Fort Worth, TX 76161

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:


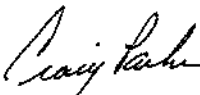
This submission is an application to register an end use pro namely EFFIPRO[®] PLUS Topical Solution for Cats. Effipro[®] EFFIPRO[®] PLUS Topical Solution for Cats contains the active ingredients Fipronil and Pyriproxyfen.

SUBMITTAL DATE:

December 16, 2011

Volume	Study Title	MRID No.
1	Administrative Materials Effipro [®] Plus Topical Solution for Cats	
	<i>Group A Product Chemistry</i>	
2	OPPTS 830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1750 Product Specific Chemistry for EFFIPRO [®] PLUS Topical Solution for Cats	48695001
3	OPPTS 830.1700 Preliminary Analysis - Quantification of the Active Ingredients Fipronil and Pyriproxyfen in Five Batches by Validated Methods	48695002
4	OPPTS 830.1800 Enforcement Analytical Method – Quantification of the Active Ingredients Fipronil and Pyriproxyfen	48695003
	<i>Group B Product Chemistry</i>	
5	OPPTS 830.6302, 830.6303, 830.6304 Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)"	48695004
6	OPPTS 830.6314 Determination of Oxidation / Reduction (Chemical Incompatibility)	48695005
7	OPPTS 830.6315 Determination of the Physico-Chemical Property "Flash Point"	48695006

Volume	Study Title	MRID No.
8	OPPTS 830.7000 Determination of the Physico-Chemical Property - pH	48695007
9	OPPTS 830.7100 Determination of Physico-Chemical Property "Viscosity"	48695008
10	OPPTS 830.7300 Determination of the Physico-Chemical Property "Relative Density"	48695009
	<i>Acute Toxicity</i>	
11	OPPTS 870.1100 Acute Oral Toxicity Study in Rats – Up-and-Down Procedure	48695010
12	OPPTS 870.1200 Acute Dermal Toxicity Study in Rats	48695011
13	OPPTS 870.2400 Acute Eye Irritation Study in Rabbits	48695012
14	OPPTS 870.2500 Acute Dermal Irritation Study in Rabbits	48695013
15	OPPTS 870.2600 Dermal sensitization - Contact Hypersensitivity in Albino Guinea Pigs, Buehler Test	48695014
	<i>Product Performance</i>	
16	OPPTS 810.3300 Summary of Efficacy Data	48695015
17	OPPTS 810.3300 Pathogen Transmission Related to Flea and Tick Infestations in Cats and Dogs	48695016
18	OPPTS 810.3300 Study of Efficacy and Safety of 636.29 in Control of Flea Infestation in the Cat	48695017
	<i>Product Safety</i>	
19	OPPTS 870.7200 Summary of Companion Animal Safety Data	48695018
20	OPPTS 870.7200 Tolerance study by Cutaneous Application (spot-on) in Young Cats.	48695019

 <div style="display: inline-block; vertical-align: middle; text-align: center;"> United States Environmental Protection Agency Washington, DC 20460 </div>		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide – Section I			
1. Company/Product Number 2382- TBA		2. EPA Product Manager Richard Gebken	
4. Company/Product (Name) Virbac AH, Inc./ EFFIPRO PLUS Topical Solution for Cats		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Virbac AH, Inc. P.O. Box 162059 Fort Worth, TX 76161 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. _____ Product Name _____	
Section - II			
<input type="checkbox"/> Amendment – Explain below		<input type="checkbox"/> Final printed labels in response to	
<input type="checkbox"/> Resubmission in response to Agency letter dated _____		<input type="checkbox"/> Agency letter dated _____ <input type="checkbox"/> "Me Too" Application	
<input type="checkbox"/> Notification – Explain below		<input checked="" type="checkbox"/> Other – Explain below	
Explanation: Use additional page(s) if necessary. (For Section I and Section II.) Application for registration. PRIA Category R310. Please refer to attached letter			
Section III			
1. Material This Product Will be Packaged in:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt 0.5.	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic, PETE <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
*Certification must be submitted		No. per container 1,3,6,36	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container	4. Size(s) Retail Container 1, 3, 6, 36 tubes		5. Location of label directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On Label accompanying product
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____	
Section IV			
1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Craig Parks, MS, DVM		Title Vice President of Research and Development	
		Telephone No. (Include Area Code) 682-647-3576	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law			6. Date Application Received (Stamped)
2. Signature 		3. Title Vice President of Research and Development	
4. Typed Name Craig Parks, MS, DVM		5. Date 12-16-11	



United States
Environmental Protection Agency
 Washington, DC 20460
Formulator's Exemption Statement
 (40 CFR 152.85)

Applicant's Name and Address

Virbac Animal Health
 P. O. Box 162059
 Ft. Worth, TX 76137

EPA File Symbol/Registration Number

2382-TBA

Product Name

EFFIPRO PLUS TOPICAL SOLUTION FOR CATS

Date of Confidential Statement of Formula (EPA Form 8570-4)

October 15, 2011

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s): pyriproxifen

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

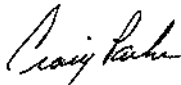
☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1)

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8750-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF

(4) The following active ingredients in this product qualify for the formulator's exemption

Source

Active Ingredient	Product Name	Registration Number
Pyriproxifen	[REDACTED]	[REDACTED]
Signature 	Name and Title Vice President, Research & Development	Date December 16, 2011

EPA Form 8570-27 (Rev. 8-95)

White - EPA copy
 Yellow - Applicant copy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number
 Virbac AH, Inc. / PO Box 162059 Fort Worth TX/ 682-647-3576

EPA Registration Number/File Symbol
 2382-TBA

Active Ingredient(s) and/or representative test compound(s)
 Fipronil, Pyriproxifen

Date
 12/16/11

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)
 indoor residential

Product Name
 Effipro Plus® Topical Solution for Cats

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Craig Parks

Date

12/16/2011

Typed or Printed Name and Title

Craig Parks, VP of Research and Development



December 16, 2011

Richard Gebken, PM 10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Child Resistant Packaging Certification
EFFIPRO PLUS Topical Solution for Cats;
EPA Reg. No. 2382-NEW

Dear Mr. Gebken:

I certify that the packaging used for the following product meets the standards of 40 CFR 157.32, including the revised standards in 16 CFR 1700.15(b), when tested by the revised testing procedures in 16 CFR 1700.20, as published in 60 FR 37710 (July 21, 1995).

- EFFIPRO PLUS Topical Solution for Cats (EPA Reg. No. 2382-NEW).

Virbac Animal Health (Virbac AH, Inc. P. O. Box 162059, Ft. Worth, TX, 76137; Company Number 2382) is submitting this child resistant packaging certification to support the pending new product application filed on the above date for EFFIPRO PLUS Topical Solution for Cats (EPA Reg. No. 2382-NEW).

Should you have any questions about this letter, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,

Craig Parker

Craig Parks, MS, DVM
Vice President, Research & Development
Virbac Animal Health, Inc.

[illegible]

Waiver Request

Registrant: Virbac Animal Health, Inc.
Acute Inhalation Study (OPPTS 830.1300).
Effipro Plus Topical Solution for Cats.

The Effipro Plus Topical Solution for Cats product is composed of 9.5 % w/w of the active ingredient Fipronil and 11.5% w/w of the active ingredient pyriproxifen. This product is packaged in single use non-refillable applicators that are intended for one time only spot-on applications to dogs.

The potential human inhalation exposure to this product is expected to be negligible. Only very small amounts of product are applied per application. Based on packaging considerations described in the proposed product labeling, the maximum volume of Effipro Plus Topical Solution for Cats that can be administered at one time to a cat using the largest available applicator size is approximately 0.5 ml. This application volume represents the worst case because it is the only dose recommended for cats or kittens.

Furthermore, the measured vapor pressure of both of the active ingredients fipronil and pyriproxifen are extremely low (2.8×10^{-9} mm Hg at 25°C and 1.0×10^{-7} mm Hg at 25°C, respectively) indicating that both active ingredients are essentially non-volatile and are therefore not expected to vaporize from the skin of the treated animal following application. The active ingredients will therefore not be available for inhalation after application according to label directions. Finally, the method of applying the liquid product directly to the pet creates no particulates, aerosols, or other respirable matter. Therefore, based on the criteria provided by the Agency in 40 CFR 158.500, footnote 4 under the Toxicology Data Requirements, a waiver of the acute inhalation study for these products is appropriate.



December 15, 2011

U.S. Bank
Government Lockbox 979074
1005 Convention Plaza
SL-MO-C2-GL
St. Louis, MO 63197

RE: Checks for 2011 PRIA Fees; Virbac AH, Inc. (EPA Co. Number 2382)

Dear Sir or Madam:

Please find enclosed two (2) checks numbered **1013436** and **1013437** made out to the Environmental Protection Agency (EPA) which are both in the amount of \$4,807.00. These checks fulfill the financial obligations in support of two amendments, to be registered under the company Virbac AH, Inc. (EPA Company Number 2382) Also attached for reference are copies of the EPA Form 8570-1 with information on the registration of the two products with EPA.

Should you have any questions about this payment, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Craig Parks", written in a cursive style.

Craig Parks, MS, DVM
Vice President, Research & Development
Virbac Animal Health, Inc.

1013437

VOID IF NOT CASHED IN 90 DAYS

CHECK AMOUNT
US DOLLARS
*****4,807.00

DATE
02-DEC-11

TO THE ORDER OF
USEPA
C/O EXPONENT
ATTN: JIM BARRON
1150 CONNECTICUT AVE, NW, STE#1100
WASHINGTON, DC 20036
United States

PAY
Four Thousand Eight Hundred Seven Dollars And Zero Cents

VIRBAC
ANIMAL HEALTH

P.O. BOX 182059
FT. WORTH, TEXAS 76161
PH. (817) 831-5030

JPMORGAN CHASE BANK, N.A.
DALLAS, TX
89-887113

VIRBAC
ANIMAL HEALTH

P.O. BOX 182059
FT. WORTH, TEXAS 76161
PH. (817) 831-5030

1013436

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1013437

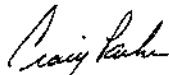


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Dated December 16, 2011			EPA Reg. No./File Symbol 2382-TBA		Page 1 of 6
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Ft. Worth, TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Test Guidelines					
830.1550	Product Identity and Composition	New Submission	Virbac AH, Inc.	OWN	
830.1600	Description of Materials Used	New Submission	Virbac AH, Inc.	OWN	
830.1620	Description of Production Process	New Submission	Virbac AH, Inc.	OWN	
830.1650	Description of Formulation Process	New Submission	Virbac AH, Inc.	OWN	
830.1670	Description of Formation of Impurities	New Submission	Virbac AH, Inc.	OWN	
830.1700	5-Batch Analysis	New Submission	Virbac AH, Inc.	OWN	
830.1750	Certified Limits	New Submission	Virbac AH, Inc.	OWN	
830.1800	Analytical Method	New Submission	Virbac AH, Inc.	OWN	
830.6302	Color	New Submission	Virbac AH, Inc.	OWN	
830.6303	Physical State	New Submission	Virbac AH, Inc.	OWN	
830.6313	Metal Stability		Virbac AH, Inc.	NR	
830.6304	Odor	New Submission	Virbac AH, Inc.	OWN	
830.6314	Oxidation/reduction	New Submission	Virbac AH, Inc.	OWN	
830.6315	Flammability	New Submission	Virbac AH, Inc.	OWN	
830.6316	Explosibility		Virbac AH, Inc.	NR	
830.6317	Storage stability	To Be Conducted	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011

EPA Form 8570-25 (9-97) Electronic and Paper Versions Available. Submit only Paper version.

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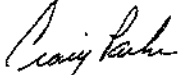


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DATA MATRIX

Date: December 16, 2011			EPA Reg No./File Symbol 2382-T13A		Page 2 of 6
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Ft. Worth, TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Group B: Series 830 – Physical and Chemical Properties					
830.7100	Viscosity	New Submission	Virbac AH, Inc.	OWN	
830.6319	Miscibility		Virbac AH, Inc.	NR	
830.6320	Corrosion characteristics	To Be Conducted	Virbac AH, Inc.	OWN	
830.6321	Dielectric breakdown voltage		Virbac AH, Inc.	NR	
830.7000	pH	New Submission	Virbac AH, Inc.	OWN	
830.7300	Density, bulk density, or specific gravity	New Submission	Virbac AH, Inc.	OWN	
830.7320	Particle size distribution		Virbac AH, Inc.	NR	
40 CFR 158.340 Toxicology Data Requirements					
870.1100	Acute oral toxicity	New Submission	Virbac AH, Inc.	OWN	
870.1200	Acute dermal toxicity	New Submission	Virbac AH, Inc.	OWN	
870.1300	Acute inhalation toxicity	Waiver	Virbac AH, Inc.	OWN	
870.2400	Primary eye irritation	New Submission	Virbac AH, Inc.	OWN	
870.2500	Primary dermal irritation	New Submission	Virbac AH, Inc.	OWN	
870.2600	Dermal sensitization	New Submission	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011

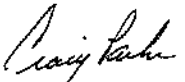


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Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Ft. Worth, TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.7200	Cat safety	43272401	Merial	OLD	
870.7200	Cat safety	43444904	Merial	OLD	
870.7200	Cat safety	43577711	Merial	OLD	
870.7200	Cat safety	43863801	Merial	OLD	
870.7200	Cat safety	43121112	Merial	OLD	
870.7200	Cat safety	44942009	Merial	PAY	
870.7200	Cat safety	44850103	Virbac	OWN	
870.7200	Cat safety	New submission	Virbac	OWN	
810.3300	Cat efficacy	43121114	Merial	OLD	
810.3300	Cat efficacy	43121115	Merial	OLD	
810.3300	Cat efficacy	43121116	Merial	OLD	
810.3300	Cat efficacy	43121118	Merial	OLD	
810.3300	Cat efficacy	43121119	Merial	OLD	
810.3300	Cat efficacy	43121120	Merial	OLD	
810.3300	Cat efficacy	43121121	Merial	OLD	
810.3300	Cat efficacy	43121122	Merial	OLD	
810.3300	Cat efficacy	43444901	Merial	OLD	
Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011

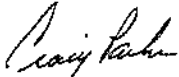


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Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Ft. Worth, TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Cat efficacy	43577701	Merial	OLD	
810.3300	Cat efficacy	43577712	Merial	OLD	
810.3300	Cat efficacy	43577713	Merial	OLD	
810.3300	Cat efficacy	43951701	Merial	OLD	
810.3300	Cat efficacy	44088901	Merial	PAY	
810.3300	Cat efficacy	44942011	Merial	PAY	
810.3300	Cat efficacy	44942106	Merial	PAY	
810.3300	Cat efficacy	45618501	Merial	PAY	
810.3300	Cat efficacy	45620502	Merial	PAY	
810.3300	Cat efficacy	45620503	Merial	PAY	
810.3300	Cat efficacy	46006002	Wellmark	PUBL	
Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011




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Date: December 16, 2011			EPA Reg. No./File Symbol 2382-TBA		Page 5 of 6
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Ft. Worth, TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS		
Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRIID Number	Submitter	Status	Note
Efficacy and Safety Data					
810.3300	Cat efficacy	45628104	Merial	PAY	
810.3300	Cat efficacy	45628105	Merial	PAY	
810.3300	Cat efficacy	44850104	Virbac	OWN	
810.3300	Cat efficacy	New submission	Virbac	OWN	
810.3300	Cat efficacy	New submission	Virbac	OWN	
810.3300	Cat efficacy	43577712	Merial	OLD	
810.3300	Cat efficacy	43121114	Merial	OLD	
810.3300	Cat efficacy	43121115	Merial	OLD	
810.3300	Cat efficacy	43121117	Merial	OLD	
810.3300	Cat efficacy	43121122	Merial	OLD	
810.3300	Cat efficacy	45620501	Merial	PAY	
810.3300	Cat efficacy	45628101	Merial	PAY	
810.3300	Cat efficacy	45628102	Merial	PAY	
810.3300	Cat efficacy	45628103	Merial	PAY	
810.3300	Cat efficacy	45628201	Merial	PAY	
810.3300	Cat efficacy	45866902	Merial	PAY	
810.3300	Cat efficacy	46019201	Merial	PAY	
810.3300	Cat efficacy	46019202	Merial	PAY	
Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011

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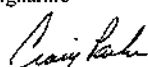


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Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Child Resistant Packaging					
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095215	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 6 applicators tube test for Child-Resistant Effectiveness	48095216	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 36 applicators tube test for Child-Resistant Effectiveness	48095217	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 1 applicator tube test for Senior-Use Effectiveness	48095218	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 6 applicators tube test for Senior-Use Effectiveness	48095219	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 36 applicators tube test for Senior-Use Effectiveness	48095220	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml applicator tube with 0.50 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410018	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml applicator tube with 0.50 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410019	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011

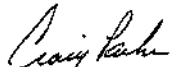


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Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Test Guidelines					
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	NR	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	NR	
			Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011

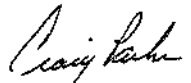


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Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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			Virbac AH, Inc.	NR	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	NR	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	NR	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Signature 		

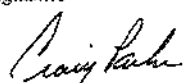


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DATA MATRIX

Date: December 16, 2011			EPA Reg No./File Symbol 2382-TBA		Page 3 of 6			
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Ft. Worth, TX 76161			Product: EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS					
Ingredient: Fipronil, Pyriproxyfen								
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note			
			Merial	OLD				
			Merial	OLD				
			Merial	OLD				
			Merial	OLD				
			Merial	OLD				
			Merial	PAY				
			Virbac	OWN				
			Virbac	OWN				
			Merial	OLD				
			Merial	OLD				
			Merial	OLD				
			Merial	OLD				
			Merial	OLD				
			Merial	OLD				
			Merial	OLD				
			Merial	OLD				
			Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011

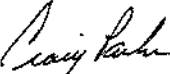


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Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Merial	OLD	
			Merial	OLD	
			Merial	OLD	
			Merial	OLD	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011


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Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Data					
			Merial	PAY	
			Merial	PAY	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Merial	OLD	
			Merial	OLD	
			Merial	OLD	
			Merial	OLD	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
			Signature 		

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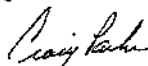


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Ingredient: Fipronil, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Child Resistant Packaging					
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
			Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks, MS, DVM Vice President, Research & Development		Date December 16, 2011




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DATA MATRIX

Date: August 23, 2011		EPA Reg No./File Symbol 87825-R		Page 1 of 6	
Applicant's/Registrant's Name & Address Virbac SA Iere avenue 2065 M - LiD F-06516 Carros, France		Product: Fipronil Technical			
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Test Guidelines					
830.1550	Product Identity and Composition	48095240, 48449201	Virbac.	OWN	
830.1600	Description of Materials Used	48095240	Virbac	OWN	
830.1620	Description of Production Process	48095239	Virbac	OWN	
830.1650	Description of Formulation Process	48095239	Virbac	OWN	
830.1670	Description of Formation of Impurities	48095240, 48449201	Virbac	OWN	
830.1700	Preliminary Analysis	48095241	Virbac	OWN	
830.1750	Certified Limits	48095240, 48449201	Virbac	OWN	
830.1800	Analytical Method	48095242	Virbac	OWN	
830.1900	Submittal of samples		Virbac	N/A	
830.6302	Color	48095240, 48095243	Virbac	OWN	
830.6303	Physical State	48095240, 48095243	Virbac	OWN	
830.6304	Odor	48095243	Virbac	OWN	
830.6313	Accelerated Storage Stability-Metal Ions	48095243	Virbac	OWN	
830.6314	Oxidation/reduction	48095239	Virbac	OWN	
830.6315	Flammability	48095239	Virbac	OWN	
830.6316	Explosibility	48095239	Virbac	NR	
830.6317	1 Yr. Storage Stability		Virbac	OWN	See note page 2
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011




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DATA MATRIX

Date August 23, 2011		EPA Reg No./File Symbol 87825-R		Page 2 of 3	
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France		Product: Fipronil Technical			
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6318	Viscosity		Virbac	N/A	
830.6319	Miscibility		Virbac	N/A	Solid
830.6320	Corrosion characteristics		Virbac	OWN	See note page 2
830.6321	Dielectric breakdown voltage		Virbac	N/A	Waived
830.7000	pH	48095247	Virbac	OWN	
830.7200	Melting Point	48095249	Virbac	OWN	
830.7300	Density bulk density or specific gravity	48095250	Virbac	OWN	
830.7320	Particle Size		Virbac	N/A	
830.7050	UV/Visible Spectrum	48095248	Virbac	OWN	
830.7370	Dissociation constant	48095251	Virbac	OWN	
830.7520;830.7550; 830.7560 830.7570	Octanol/water partition coefficient	48095244	Virbac	OWN	
830.7840;830.7860	Solubility	48095245	Virbac	OWN	
830.7950	Vapor pressure	48095246	Virbac	OWN	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

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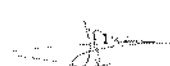
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Date: August 23, 2011		EPA Reg No./File Symbol 87825-R		Page 3 of 6	
Applicant's/Registrant's Name & Address Virbac SA 1ere Avenue 2065 M - LID F-06516 Carros, France		Product: Fipronil Technical			
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 158.340 Toxicology Data Requirements					
870.1100	Acute oral toxicity	42918628; 43235401 43279706	BASF	OLD	
870.1200	Acute dermal toxicity	42918629	BASF	OLD	
870.1200	Acute dermal toxicity	43235402	BASF	OLD	
870.1300	Acute inhalation toxicity	42918631	BASF	OLD	
870.2400	Primary eye irritation	42918632	BASF	OLD	
870.2500	Primary dermal irritation	42918630	BASF	OLD	
870.2600	Dermal sensitization	42918634	BASF	OLD	
870.6100	Acute delayed neurotoxicity	42918635	BASF	OLD	
870.6100	Acute delayed neurotoxicity	43559501	BASF	OLD	
870.3100	90-day oral toxicity - rodent	42918643	BASF	OLD	
870.3150	90-day oral toxicity - nonrodent	42918642	BASF	OLD	
870.3200	21-day dermal toxicity	42918644	BASF	OLD	
870.3250	90-day dermal toxicity	DATA GAP	BASF	GAP	*See below
870.6100	90-day neurotoxicity - mammal	43291703	BASF	OLD	
81-8	Neurotoxicity to Rats by Acute Oral Administration	44431801	BASF	PAY	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011




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Applicant's/Registrant's Name & Address Virbac SA 1 ere avenue 2065 M - LID F-06516 Carros, France		Product: Fipronil Technical			
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 158.340 Toxicology Data Requirements (Continued)					
84-2	Structural chromosomal aberration	42918680	BASF	OLD	
84-2	Structural chromosomal aberration	42918653	BASF	OLD	
84-2	Other genotoxic effects	42918651;42918653 43501703	BASF	OLD	
85-1/870.7485	General metabolism	42918655	BASF	OLD	
85-1/870.7485	General metabolism	43253701	BASF	PAY	
85-1/870.7485	General metabolism	43737308	BASF	OLD	
85-1/870.7485	General metabolism	42918654	BASF	OLD	
85-1/870.7485	General metabolism	42977904	BASF	OLD	
85-1/870.7485	General metabolism	43253701	BASF	OLD	
85-2/870.7600	Dermal penetration	43737308	BASF	PAY	
85-7/870.7600	Immunotoxicity	DATA GAP		GAP	*See below
40 CFR 158.490 Wildlife and Aquatic Organisms Data Requirements				OLD	
71-1/850.2100	Avian oral LD 50 – mallard or bobwhite	42918617 42918616	BASF	OLD	
72-1/850.1075	Freshwater fish LC 50 – rainbow or bluegill	42918624;42918673; 42918674;42977902 43279703;43291718	BASF	OLD OLD OLD	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011




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Date: August 23, 2011			EPA Reg. No./File Symbol 87825-R		Page 5 of 5
Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
83-1/870.4100	Chronic feeding - rodent	42918648	BASF	OLD	
83-1/870.4100	Chronic feeding - nonrodent	42918645	BASF	OLD	
83-1/870.4100	Chronic feeding - nonrodent	43402802	BASF	PAY	
83-2/870.4200	Oncogenicity - mouse	42918649	BASF	OLD	
83-2/870.4200	Oncogenicity - mouse	43501702	BASF	PAY	
83-2/870.4200	Oncogenicity - rat	42918648	BASF	OLD	
83-3/870.3700	Teratogenicity - rabbit	42918646	BASF	OLD	
83-3/870.3700	Teratogenicity - rat	42977903	BASF	OLD	
83-3/870.3700	Teratogenicity - rat	44275001	BASF	PAY	
83-6/870.6300	Developmental neurotoxicity	44039002	BASF	PAY	
83-4/870.3800	Reproduction	42918647	BASF	OLD	
84-2/870.5100	Gene mutation	42918652	BASF	OLD	
84-2/870.5100	Gene mutation	42918679	BASF	OLD	
84-2/870.5100	Gene mutation	43291716	BASF	OLD	
84-2/870.5100	Gene mutation	43291717	BASF	OLD	
84-2/870.5100	Gene mutation	43291721	BASF	OLD	
84-2/870.5100	Gene mutation	43291722	BASF	OLD	
84-2/870.5100	Gene mutation	43401102	BASF	OLD	
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Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
72-2/850.1010	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	42918625	BASF	OLD	
	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	42918669	BASF	OLD	
	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	42918671	BASF	OLD	
	Acute LC 50 freshwater invertebrates (<i>Daphnia magna</i>)	43291719	BASF	OLD	
835.2110	Hydrolysis	42977905	BASF	OLD	
40 CFR 158.390 Reentry Protection Data Requirements					
133-3	Dermal exposure - Fipronil	44433302	Merial	PAY	
133-4	Inhalation exposure - Fipronil	44433302	Merial	PAY	
132-1	Dislodgeable residue dissipation - Fipronil	44531203	Merial	PAY	
N/A	Dermal and inhalation exposure of commercial pet groomers (Spot) - Fipronil	44433303	Merial	PAY	
N/A	Analytical method for exposure studies - Fipronil	44433308	Merial	PAY	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		August 23, 2011

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* Pursuant to 40 CFR 152.96(c), Virbac hereby certifies that Virbac has no basis to believe that this requirement is not a data gap and, further, that Virbac has sent by certified mail to all companies on the current EPA Data Submitters List for fipronil a letter requesting that the company identify, within 60 days of receipt, any valid study that would fulfill this data requirement. Once this 60-day period expires, Virbac will update the Agency as to the information, if any, Virbac receives in response to this "data gap" letter.




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Applicant's/Registrant's Name & Address Virbac SA 1 rue avenue 2065 M - LID F-06516 Carros, France		Product: Fipronil Technical			
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Test Guidelines					
			Virbac.	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	N/A	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	NR	
			Virbac	OWN	See note page 2
Signature 		Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011	




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Applicant's/Registrant's Name & Address Virbac SA Iere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Virbac	N/A	
			Virbac	N/A	Solid
			Virbac	OWN	See note page 2
			Virbac	N/A	Waived
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	N/A	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
			Virbac	OWN	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011

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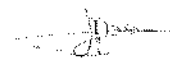
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Applicant's/Registrant's Name & Address Virbac SA Iere avenue 2065 M - LID F-06516 Carros, France		Product: Fipronil Technical			
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 158.340 Toxicology Data Requirements					
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
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Signature 		Name and Title Jean-Pascal Marc Corporate Product Innovation Director		Date August 23, 2011	



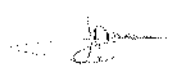
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DATA MATRIX

Date: August 23, 2011			EPA Reg No./File Symbol: 87825-R		Page 4 of 6
Applicant's/Registrant's Name & Address Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France			Product: Fipronil Technical		
Ingredient: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	OLD	
			BASF	PAY	
			BASF	OLD	
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			Signature 		



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DATA MATRIX

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Virbac SA 1ere avenue 2065 M - LID F-06516 Carros, France		Product: Fipronil Technical			
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF	OLD	
			BASF	OLD	
			BASF	PAY	
			BASF	OLD	
			BASF	PAY	
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			Signature		

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF	OLD	
			BASF	OLD	
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			Merial	PAY	
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			Merial	PAY	
			Merial	PAY	
			Merial	PAY	
Signature 			Name and Title Jean-Pascal Marc Corporate Product Innovation Director		August 23, 2011

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* Pursuant to 40 CFR 152.96 (c), Virbac hereby certifies that Virbac has no basis to believe that this requirement is not a data gap and, further, that Virbac has sent by certified mail to all companies on the current EPA Data Submitters List for fipronil a letter requesting that the company identify, within 60 days of receipt, any valid study that would fulfill this data requirement. Once this 60-day period expires, Virbac will update the Agency as to the information, if any, Virbac receives in response to this "data gap" letter.

